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(54) Title: METHODS AND APPARATUS FOR TREATING INTERVERTEBRAL DISCS

(57) Abstract: Apparatus and methods for treating a target tissue by delivering a fluid at a defined temperature to a patient's body. An apparatus of the invention includes a fluid delivery unit for delivering fluid in at least close proximity to the target tissue, an aspiration unit for withdrawing the fluid, and a fluid source unit for providing the fluid at the defined temperature. A method of the invention includes forming a void in at least close proximity to the target tissue, and circulating a preheated fluid through the void, wherein the target tissue undergoes adjustment from body temperature to a treatment temperature due to heat exchange between the fluid and the target tissue.

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Patent Application No. 09/074,020, filed on May 6, 1998 (Attorney Docket No. E-6), U.S. Patent Application No. 09/010,382, filed January 21, 1998, now U.S. Patent No. 6,190,381 (Attorney Docket A-6), U.S. Patent Application No. 09/032,375, filed February 27, 1998 (Attorney Docket No. CB-3), U.S. Patent Application Nos. 08/977,845, filed on November 25, 1997, now U.S. Patent No. 6,210,402 (Attorney Docket No. D-2), 08/942,580, filed on October 2, 1997, now U.S. Patent No. 6,159,194 (Attorney Docket No. 16238-001300), U.S. Patent Application No. 08/753,227, filed on November 22, 1996, now U.S. Patent No. 5,873,855 (Docket 16238-002200), U.S. Patent Application No. 08/687792, filed on July 18, 1996, now U.S. Patent No. 5,843,019 (Docket No. 16238-001600), and PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, now U.S. Patent No. 5,697,909 (Attorney Docket 16238-000440), which was a continuation-in-part of U.S. Patent Application No. 08/059,681, filed on May 10, 1993, now abandoned (Attorney Docket 16238-000420), which was a continuation-in-part of U.S. Patent Application No. 07/958,977, filed on October 9, 1992, now U.S. Patent No. 5,366,443 (Attorney Docket 16238-000410) which was a continuation-in-part of U.S. Patent Application No. 07/817,575, filed on January 7, 1992, abandoned (Attorney Docket 16238-00040), the complete disclosures of which are incorporated herein by reference for all purposes. The present invention is also related to commonly assigned U.S. Patent No. 5,697,882, filed November 22, 1995 (Attorney Docket 16238-000700), the complete disclosure of which is incorporated herein by reference for all purposes.

BACKGROUND OF THE INVENTION

The present invention relates to the field of electrosurgery, and more particularly to surgical devices and methods which employ high frequency electrical energy to treat tissue in regions of the spine. The present invention also relates to formation of a void within tissue of an intervertebral disc. The present invention also relates to the treatment of disc tissue with a heated fluid.

The major causes of persistent, often disabling, back pain are disruption of the disc annulus, chronic inflammation of the disc, contained and non-contained herniation, and relative instability of the vertebral bodies surrounding a given disc, such as the instability that often occurs due to a stretching of the interspinous tissue surrounding the vertebrae. Intervertebral discs mainly function to cushion and tether the

addition, the risk of instability from ligament and bone removal is generally lower in endoscopic procedures than with open procedures. Further, more rapid rehabilitation facilitates faster recovery and return to work.

Minimally invasive techniques for the treatment of spinal diseases or disorders include chemonucleolysis, laser techniques, and mechanical techniques. These procedures generally require the surgeon to form a passage or operating corridor from the external surface of the patient to the spinal disc(s) for passage of surgical instruments, implants and the like. Typically, the formation of this operating corridor requires the removal of soft tissue, muscle or other types of tissue depending on the procedure (i.e., laparascopic, thoracoscopic, arthroscopic, back, etc.). This tissue is usually removed with mechanical instruments, such as pituitary rongeurs, curettes, graspers, cutters, drills, microdebriders and the like. Unfortunately, these mechanical instruments greatly lengthen and increase the complexity of the procedure. In addition, these instruments might sever blood vessels within this tissue, usually causing profuse bleeding that obstructs the surgeon's view of the target site.

Once the operating corridor is established, the nerve root is retracted and a portion or all of the disc is removed with mechanical instruments, such as a pituitary rongeur. In addition to the above problems with mechanical instruments, there are serious concerns because these instruments are not precise, and it is often difficult, during the procedure, to differentiate between the target disc tissue, and other structures within the spine, such as bone, cartilage, ligaments, nerves and non-target tissue. Thus, the surgeon must be extremely careful to minimize damage to the cartilage and bone within the spine, and to avoid damaging nerves, such as the spinal nerves and the dura mater surrounding the spinal cord.

Lasers were initially considered ideal for spine surgery because lasers ablate or vaporize tissue with heat, which also acts to cauterize and seal the small blood vessels in the tissue. Unfortunately, lasers are both expensive and somewhat tedious to use in these procedures. Another disadvantage with lasers is the difficulty in judging the depth of tissue ablation. Since the surgeon generally points and shoots the laser without contacting the tissue, he or she does not receive any tactile feedback to judge how deeply the laser is cutting. Because healthy tissue, bones, ligaments and spinal nerves often lie within close proximity of the spinal disc, it is essential to maintain a minimum depth of tissue damage, which cannot always be ensured with a laser.

provides methods for ablation of disc tissue and exposure of disc tissue to a controlled temperature regime during a percutaneous procedure, wherein the volume of the disc is decreased and discogenic pain is alleviated.

SUMMARY OF THE INVENTION

The present invention provides systems, apparatus, and methods for selectively applying electrical energy and thermal energy to structures within a patient's body, such as the intervertebral disc. The systems and methods of the present invention are useful for shrinkage, ablation, resection, aspiration, and/or hemostasis of tissue and other body structures in open and endoscopic spine surgery. In particular, the present invention includes a method and system for debulking, ablating, and shrinking the disc by exposing disc tissue to a fluid at a controlled temperature.

The present invention further relates to an electrosurgical probe including an elongated shaft having first and second curves in the distal end portion of the shaft, wherein the shaft can be rotated within an intervertebral disc to contact fresh tissue of the nucleus pulposus. The present invention also relates to an electrosurgical probe including an elongated shaft, wherein the shaft distal end can be guided to a specific target site within a disc, and the shaft distal end is adapted for localized ablation of targeted disc tissue. The present invention further relates to a probe having an elongated shaft, wherein the shaft includes an active electrode, an insulating collar, and an outer shield, and wherein the active electrode includes a head having an apical spike and a cusp. The present invention still further relates to a method for ablating disc tissue with an electrosurgical probe, wherein the probe includes an elongated shaft, and the shaft distal end is guided to a specific target site within a disc.

In one aspect, the present invention provides a method of treating a herniated intervertebral disc. The method comprises positioning at least one active electrode within the intervertebral disc. High frequency voltage is applied between the active electrode(s) and one or more return electrode(s) to debulk, ablate, coagulate and/or shrink at least a portion of the nucleus pulposus and/or annulus. The high frequency voltage effects a controlled depth of thermal heating to reduce the water content of the nucleus pulposus, thereby debulking the nucleus pulposus and reducing the internal pressure on the annulus fibrosus.

In an exemplary embodiment, an electrically conductive media, such as isotonic saline or an electrically conductive gel, is delivered to the target site within the

tissue structures. A more complete description of this phenomenon is described in commonly assigned U.S. Patent No. 5,697,882 the complete disclosure of which is incorporated herein by reference.

An apparatus according to the present invention generally includes a shaft having proximal and distal end portions, an active electrode at the distal end and one or more connectors for coupling the active electrode to a source of high frequency electrical energy. The probe or catheter may assume a wide variety of configurations, with the primary purpose being to introduce the electrode assembly into the patient's disc (in an open or endoscopic procedure) and to permit the treating physician to manipulate the electrode assembly from a proximal end of the shaft. The probe shaft can be flexible, curved, or steerable so as to allow the treating physician to move the active electrode into close proximity of the region of the disc, e.g., herniation, to be treated. The electrode assembly includes one or more active electrode(s) and a return electrode spaced from the active electrode(s) either on the instrument shaft or separate from the instrument shaft.

The active electrode(s) may comprise a single active electrode, or an electrode array, extending from an electrically insulating support member, typically made of an inorganic material such as ceramic, silicone rubber, or glass. The active electrode will usually have a smaller exposed surface area than the return electrode, such that the current densities are much higher at the active electrode than at the return electrode. In one embodiment, the return electrode has a relatively large, smooth surface extending around the instrument shaft to reduce current densities, thereby minimizing damage to adjacent tissue.

In another aspect, the present invention provides a method of treating an intervertebral disc, the method comprising contacting at least a first region of the intervertebral disc with at least one active electrode of an electrosurgical probe. The at least one active electrode may be disposed on the distal end portion of a shaft of the electrosurgical probe. A first high frequency voltage is applied between the active electrode(s) and one or more return electrode(s) such that at least a portion of the nucleus pulposus is ablated, and the volume of the disc's nucleus pulposus is decreased. After ablation of disc tissue at the first region of the intervertebral disc, other regions of the disc may be contacted with the at least one active electrode for ablation of disc tissue at the other regions of the disc. In one embodiment of the invention, axial translation of the at least one active electrode within the disc while applying the first high frequency voltage, leads to formation of a channel or void within the treated disc. The diameter of such a

penetration of the shaft into a disc can be monitored by one or more depth markings on the shaft.

In another aspect of the invention, the method further comprises retracting the shaft distal end portion proximally within the lumen of the introducer needle, wherein the at least one active electrode does not make contact with the needle distal end.

In another aspect of the invention, the shaft of the electrosurgical system includes a shield, and a distal insulating collar. In yet another aspect of the invention, the at least one active electrode includes an apical spike and a cusp. Applicants have found that an active electrode having an apical spike and a cusp promotes high current density in the vicinity of the active electrode.

In another aspect of the invention, an electrosurgical apparatus includes an introducer needle having a lumen, an introducer extension tube adapted for passage within the needle lumen, and a probe having a shaft adapted for passage within the introducer extension tube. The shaft may be bent, biased, or steerable to facilitate guiding or steering the shaft into at least close proximity to a target tissue. The introducer extension tube may be advanced or retracted within the introducer needle to define a starting point from where the shaft is to be guided. In one embodiment, such an apparatus is adapted for positioning a distal end of the probe shaft at a specific location within an intervertebral disc.

In another embodiment, the present invention provides an apparatus for providing a fluid at a controlled temperature and for delivering the fluid to a void within a patient's body. The apparatus includes a shaft having a shaft distal or working end, a fluid delivery unit adapted for delivering the fluid from the shaft distal end to the void, and a fluid source unit for providing the fluid to the fluid delivery unit. The apparatus may further include an aspiration unit adapted for removing the fluid from the vicinity of the shaft distal end or from the void, in order to allow the exchange or circulation of the fluid through the void or through the patient's body. Typically, the fluid source unit includes a fluid reservoir for holding the fluid at the controlled temperature, a temperature control unit for controlling the temperature of the fluid in the fluid reservoir, and a flow control unit for regulating the rate at which the fluid is provided to the fluid delivery unit. The fluid source unit may further include a heating unit and a cooling unit, for heating and cooling the fluid, respectively. The apparatus may further include an electrode assembly disposed at the shaft distal end for forming the void via electrosurgical ablation (e.g., via Coblation®).

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an electrosurgical system incorporating a power supply and an electrosurgical probe for tissue ablation, resection, incision, contraction and for vessel hemostasis according to the present invention;

Fig. 2 schematically illustrates one embodiment of a power supply according to the present invention;

Fig. 3 illustrates an electrosurgical system incorporating a plurality of active electrodes and associated current limiting elements;

Fig. 4 is a side view of an electrosurgical probe according to the present invention;

Fig. 5 is a view of the distal end portion of the probe of Fig. 4

Fig. 6 is an exploded view of a proximal portion of an electrosurgical probe;

Figs. 7A and 7B are perspective and end views, respectively, of an alternative electrosurgical probe incorporating an inner fluid lumen;

Figs. 8A-8C are cross-sectional views of the distal portions of three different embodiments of an electrosurgical probe according to the present invention;

Figs. 9-12 are end views of alternative embodiments of the probe of Fig. 4, incorporating aspiration electrode(s);

Fig. 13 is a side view of the distal portion of the shaft of an electrosurgical probe, according to one embodiment of the invention;

Figs. 14A-14C illustrate an alternative embodiment incorporating a screen electrode;

Figs. 15A-15D illustrate four embodiments of electrosurgical probes specifically designed for treating spinal defects;

Fig. 16 illustrates an electrosurgical system incorporating a dispersive return pad for monopolar and/or bipolar operations;

Fig. 17 illustrates a catheter system for electrosurgical treatment of intervertebral discs according to the present invention;

Figs. 18-22 illustrate a method of performing a microendoscopic discectomy according to the principles of the present invention;

Fig. 35 schematically represents a series of steps involved in a method of making an electrosurgical probe of the present invention;

Fig. 36A schematically represents a normal intervertebral disc in relation to the spinal cord;

Fig. 36B schematically represents an intervertebral disc exhibiting a protrusion of the nucleus pulposus and a concomitant distortion of the annulus fibrosus;

Fig. 36C schematically represents an intervertebral disc exhibiting a plurality of fissures within the annulus fibrosus and a concomitant distortion of the annulus fibrosus;

Fig. 36D schematically represents an intervertebral disc exhibiting fragmentation of the nucleus pulposus and a concomitant distortion of the annulus fibrosus;

Fig. 37 schematically represents translation of a curved shaft of an electrosurgical probe within the nucleus pulposus for treatment of an intervertebral disc;

Fig. 38 shows a shaft of an electrosurgical probe within an intervertebral disc, wherein the shaft distal end is targeted to a specific site within the disc;

Fig. 39 schematically represents a series of steps involved in a method of ablating disc tissue according to the present invention;

Fig. 40 schematically represents a series of steps involved in a method of guiding an electrosurgical probe to a target site within an intervertebral disc for ablation of targeted disc tissue, according to another embodiment of the invention;

Fig. 41 shows treatment of an intervertebral disc using an electrosurgical probe and a separately introduced ancillary device, according to another embodiment of the invention;

Fig. 42 is a side view of an electrosurgical probe having a tracking device;.

Fig. 43A shows a steerable electrosurgical probe wherein the shaft of the probe assumes a substantially linear configuration;

Fig. 43B shows the steerable electrosurgical probe of Fig. 44A, wherein the shaft distal end of the probe adopts a bent configuration;

Fig. 44 shows a steerable electrosurgical probe and an ancillary device inserted within the nucleus pulposus of an intervertebral disc;

Fig. 45A shows the shaft distal end of an electrosurgical probe positioned within an introducer extension tube and within an introducer needle;

DESCRIPTION OF SPECIFIC EMBODIMENTS

The present invention provides systems and methods for selectively applying electrical energy to a target location within or on a patient's body, particularly including support tissue or other body structures in the spine. These procedures include treating interspinous tissue, degenerative discs, laminectomy/discectomy procedures for treating herniated discs, decompressive laminectomy for stenosis in the lumbosacral and cervical spine, localized tears or fissures in the annulus, nucleotomy, disc fusion procedures, medial facetectomy, posterior lumbosacral and cervical spine fusions, treatment of scoliosis associated with vertebral disease, foraminotomies to remove the roof of the intervertebral foramina to relieve nerve root compression and anterior cervical and lumbar discectomies. These procedures may be performed through open procedures, or using minimally invasive techniques, such as thoracoscopy, arthroscopy, laparascopy or the like.

The present invention involves techniques for treating disc abnormalities with RF energy. In some embodiments, RF energy is used to ablate, debulk and/or stiffen the tissue structure of the disc to reduce the volume of the disc, thereby relieving neck and back pain. In one aspect of the invention, spinal disc tissue is volumetrically removed or ablated to form one or more voids, holes, channels, divots, or other spaces within the disc. In this procedure, a high frequency voltage difference is applied between one or more active electrode(s) and one or more return electrode(s) to develop high electric field intensities in the vicinity of the target tissue. The high electric field intensities adjacent the active electrode(s) lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). Applicant believes that the tissue structure is volumetrically removed through molecular disintegration of larger organic molecules into smaller molecules and/or atoms, such as hydrogen, oxygen, oxides of carbon, hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to dehydrating the tissue material by the removal of liquid within the cells of the tissue and extracellular fluids, as is typically the case with electrosurgical desiccation and vaporization.

The present invention also involves a system and method for treating the interspinous tissue (e.g., tendons, cartilage, synovial tissue in between the vertebrae, and other support tissue within and surrounding the vertebral column). In some embodiments, RF energy is used to heat and shrink the interspinous tissue to stabilize the vertebral

electrons (e.g., 3.5 eV to 5 eV) can subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

Plasmas may be formed by heating a gas and ionizing the gas by driving an electric current through it, or by shining radio waves into the gas. Generally, these methods of plasma formation give energy to free electrons in the plasma directly, and then electron-atom collisions liberate more electrons, and the process cascades until the desired degree of ionization is achieved. Often, the electrons carry the electrical current or absorb the radio waves and, therefore, are hotter than the ions. Thus, in applicant's invention, the electrons, which are carried away from the tissue towards the return electrode, carry most of the plasma's heat with them, allowing the ions to break apart the tissue molecules in a substantially non-thermal manner.

In some embodiments, the present invention applies high frequency (RF) electrical energy in an electrically conducting media environment to shrink or remove (i.e., resect, cut, or ablate) a tissue structure and to seal transected vessels within the region of the target tissue. The present invention may also be useful for sealing larger arterial vessels, e.g., on the order of about 1 mm in diameter. In some embodiments, a high frequency power supply is provided having an ablation mode, wherein a first voltage is applied to an active electrode sufficient to effect molecular dissociation or disintegration of the tissue, and a coagulation mode, wherein a second, lower voltage is applied to an active electrode (either the same or a different electrode) sufficient to heat, shrink, and/or achieve hemostasis of severed vessels within the tissue. In other embodiments, an electrosurgical instrument is provided having one or more coagulation electrode(s) configured for sealing a severed vessel, such as an arterial vessel, and one or more active electrodes configured for either contracting the collagen fibers within the tissue or removing (ablating) the tissue, e.g., by applying sufficient energy to the tissue to effect molecular dissociation. In the latter embodiments, the coagulation electrode(s) may be configured such that a single voltage can be applied to coagulate with the coagulation electrode(s), and to ablate or shrink with the active electrode(s). In other embodiments, the power supply is combined with the coagulation instrument such that the coagulation electrode is used when the power supply is in the coagulation mode (low voltage), and the active electrode(s) are used when the power supply is in the ablation mode (higher voltage).

precise depth is critical to the achievement of therapeutic collagen shrinkage. A more detailed description of collagen shrinkage can be found in U.S. Patent Application No. 08/942,580 filed on October 2, 1997, (Attorney Docket No. 16238-001300), the complete disclosure of which is incorporated by reference.

The preferred depth of heating to effect the shrinkage of collagen in the heated region (i.e., the depth to which the tissue is elevated to temperatures between 60°C to 70°C) generally depends on (1) the thickness of the target tissue, (2) the location of nearby structures (e.g., nerves) that should not be exposed to damaging temperatures, and/or (3) the location of the collagen tissue layer within which therapeutic shrinkage is to be effected. The depth of heating is usually in the range from 1.0 mm to 5.0 mm. In some embodiments of the present invention, the tissue is purposely damaged in a thermal heating mode to create necrosed or scarred tissue at the tissue surface. The high frequency voltage in the thermal heating mode is below the threshold of ablation as described above, but sufficient to cause some thermal damage to the tissue immediately surrounding the electrodes without vaporizing or otherwise debulking this tissue *in situ*. Typically, it is desired to achieve a tissue temperature in the range of about 60°C to 100°C to a depth of about 0.2 mm to 5 mm, usually about 1 mm to 2 mm. The voltage required for this thermal damage will partly depend on the electrode configurations, the conductivity of the area immediately surrounding the electrodes, the time period in which the voltage is applied and the depth of tissue damage desired. With the electrode configurations described in this application (e.g., Figs. 15A-15D), the voltage level for thermal heating will usually be in the range of about 20 volts rms to 300 volts rms, preferably about 60 volts rms to 200 volts rms. The peak-to-peak voltages for thermal heating with a square wave form having a crest factor of about 2 are typically in the range of about 40 volts peak-to-peak to 600 volts peak-to-peak, preferably about 120 volts peak-to-peak to 400 volts peak-to-peak. In some embodiments, capacitors or other electrical elements may be used to increase the crest factor up to 10. The higher the voltage is within this range, the less time required. If the voltage is too high, however, the surface tissue may be vaporized, debulked or ablated, which is generally undesirable.

In yet another embodiment, the present invention may be used for treating degenerative discs with fissures or tears. In these embodiments, the active and return electrode(s) are positioned in or around the inner wall of the disc annulus such that the active electrode is adjacent to the fissure. High frequency voltage is applied between the

either individually or to the complete array of electrodes, if and when the tissue encountered at the tip or working end of the probe is normal tissue based on the measured electrical properties.

In one embodiment, the current limiting elements (discussed in detail above) are configured such that the active electrodes will shut down or turn off when the electrical impedance reaches a threshold level. When this threshold level is set to the impedance of the fatty tissue surrounding nerves, the active electrodes will shut off whenever they come in contact with, or in close proximity to, nerves. Meanwhile, the other active electrodes, which are in contact with or in close proximity to tissue, will continue to conduct electric current to the return electrode. This selective ablation or removal of lower impedance tissue in combination with the Coblation® mechanism of the present invention allows the surgeon to precisely remove tissue around nerves or bone. Applicant has found that the present invention is capable of volumetrically removing tissue closely adjacent to nerves without impairment the function of the nerves, and without significantly damaging the tissue of the epineurium. One of the significant drawbacks with the prior art microdebriders, conventional electrosurgical devices and lasers is that these devices do not differentiate between the target tissue and the surrounding nerves or bone. Therefore, the surgeon must be extremely careful during these procedures to avoid damage to the bone or nerves within and around the nasal cavity. In the present invention, the Coblation® process for removing tissue results in extremely small depths of collateral tissue damage as discussed above. This allows the surgeon to remove tissue close to a nerve without causing collateral damage to the nerve fibers.

In addition to the above, applicant has discovered that the Coblation® mechanism of the present invention can be manipulated to ablate or remove certain tissue structures, while having little effect on other tissue structures. As discussed above, the present invention uses a technique of vaporizing electrically conductive fluid to form a plasma layer or pocket around the active electrode(s), and then inducing the discharge of energy from this plasma or vapor layer to break the molecular bonds of the tissue structure. Based on initial experiments, applicants believe that the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 10^{20} atoms/cm^3 for aqueous solutions), the electron mean free path increases to enable subsequently

through the dissociation or disintegration of organic molecules into non-viable atoms and molecules. Specifically, the present invention converts the solid tissue cells into non-condensable gases that are no longer intact or viable, and thus, not capable of spreading viable tumor particles to other portions of the patient's brain or to the surgical staff. The high frequency voltage is preferably selected to effect controlled removal of these tissue cells while minimizing substantial tissue necrosis to surrounding or underlying tissue. A more complete description of this phenomena can be found in co-pending U.S. Patent Application 09/109,219, filed June 30, 1998 (Attorney Docket No. CB-1), the complete disclosure of which is incorporated herein by reference.

The electrosurgical probe or catheter of the present invention can comprise a shaft or a handpiece having a proximal end and a distal end which supports one or more active electrode(s). The shaft or handpiece may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft.

For endoscopic procedures within the spine, the shaft will have a suitable diameter and length to allow the surgeon to reach the target site (e.g., a disc or vertebra) by delivering the shaft through the thoracic cavity, the abdomen or the like. Thus, the shaft will usually have a length in the range of about 5.0 cm to 30.0 cm, and a diameter in the range of about 0.2 mm to about 20 mm. Alternatively, the shaft may be delivered directly through the patient's back in a posterior approach, which would considerably reduce the required length of the shaft. In any of these embodiments, the shaft may also be introduced through rigid or flexible endoscopes. Alternatively, the shaft may be a flexible catheter that is introduced through a percutaneous penetration in the patient. Specific shaft designs will be described in detail in connection with the figures hereinafter.

In an alternative embodiment, the probe may comprise a long, thin needle (e.g., on the order of about 1 mm in diameter or less) that can be percutaneously

In some embodiments, the active electrode(s) have an active portion or surface with surface geometries shaped to promote the electric field intensity and associated current density along the leading edges of the electrodes. Suitable surface geometries may be obtained by creating electrode shapes that include preferential sharp edges, or by creating asperities or other surface roughness on the active surface(s) of the electrodes. Electrode shapes according to the present invention can include the use of formed wire (e.g., by drawing round wire through a shaping die) to form electrodes with a variety of cross-sectional shapes, such as square, rectangular, L or V shaped, or the like. Electrode edges may also be created by removing a portion of the elongate metal electrode to reshape the cross-section. For example, material can be ground along the length of a round or hollow wire electrode to form D or C shaped wires, respectively, with edges facing in the cutting direction. Alternatively, material can be removed at closely spaced intervals along the electrode length to form transverse grooves, slots, threads or the like along the electrodes.

Additionally or alternatively, the active electrode surface(s) may be modified through chemical, electrochemical or abrasive methods to create a multiplicity of surface asperities on the electrode surface. These surface asperities will promote high electric field intensities between the active electrode surface(s) and the target tissue to facilitate ablation or cutting of the tissue. For example, surface asperities may be created by etching the active electrodes with etchants having a pH less than 7.0 or by using a high velocity stream of abrasive particles (e.g., grit blasting) to create asperities on the surface of an elongated electrode. A more detailed description of such electrode configurations can be found in U.S. Patent No. 5,843,019, the complete disclosure of which is incorporated herein by reference.

The return electrode is typically spaced proximally from the active electrode(s) a suitable distance to avoid electrical shorting between the active and return electrodes in the presence of electrically conductive fluid. In most of the embodiments described herein, the distal edge of the exposed surface of the return electrode is spaced about 0.5 mm to 25 mm from the proximal edge of the exposed surface of the active electrode(s), preferably about 1.0 mm to 5.0 mm. Of course, this distance may vary with different voltage ranges, conductive fluids, and depending on the proximity of tissue structures to active and return electrodes. The return electrode will typically have an exposed length in the range of about 1 mm to 20 mm.

on another instrument, coupled to a suitable vacuum source for aspirating fluids from the target site. In addition, the invention may include one or more aspiration electrode(s) coupled to the distal end of the suction lumen for ablating, or at least reducing the volume of, non-ablated tissue fragments that are aspirated into the lumen. The aspiration electrode(s) function mainly to inhibit clogging of the lumen that may otherwise occur as larger tissue fragments are drawn therein. The aspiration electrode(s) may be different from the ablation active electrode(s), or the same electrode(s) may serve both functions. A more complete description of instruments incorporating aspiration electrode(s) can be found in commonly assigned, co-pending U.S. Patent Application No. 09/010,382 filed January 21, 1998, the complete disclosure of which is incorporated herein by reference.

As an alternative or in addition to suction, it may be desirable to contain the excess electrically conductive fluid, tissue fragments and/or gaseous products of ablation at or near the target site with a containment apparatus, such as a basket, retractable sheath, or the like. This embodiment has the advantage of ensuring that the conductive fluid, tissue fragments or ablation products do not flow through the patient's vasculature or into other portions of the body. In addition, it may be desirable to limit the amount of suction to limit the undesirable effect suction may have on hemostasis of severed blood vessels.

The present invention may use a single active electrode or an array of active electrodes spaced around the distal surface of a catheter or probe. In the latter embodiment, the electrode array usually includes a plurality of independently current-limited and/or power-controlled active electrodes to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive fluids, such as blood, normal saline, and the like. The active electrodes may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other active electrodes. Alternatively, the active electrodes may be connected to each other at either the proximal or distal ends of the catheter to form a single wire that couples to a power source.

In one configuration, each individual active electrode in the electrode array is electrically insulated from all other active electrodes in the array within said instrument and is connected to a power source which is isolated from each of the other active electrodes in the array or to circuitry which limits or interrupts current flow to the active

The application of a high frequency voltage between the return electrode(s) and the active electrode(s) for appropriate time intervals effects shrinking, cutting, removing, ablating, shaping, contracting or otherwise modifying the target tissue. In some embodiments of the present invention, the tissue volume over which energy is dissipated (i.e., a high current density exists) may be more precisely controlled, for example, by the use of a multiplicity of small active electrodes whose effective diameters or principal dimensions range from about 10 mm to 0.01 mm, preferably from about 2 mm to 0.05 mm, and more preferably from about 1 mm to 0.1 mm. In this embodiment, electrode areas for both circular and non-circular terminals will have a contact area (per active electrode) below 50 mm^2 for electrode arrays and as large as 75 mm^2 for single electrode embodiments. In multiple electrode array embodiments, the contact area of each active electrode is typically in the range from 0.0001 mm^2 to 1 mm^2, and more preferably from 0.001 mm^2 to .5 mm^2. The circumscribed area of the electrode array or active electrode is in the range from 0.25 mm^2 to 75 mm^2, preferably from 0.5 mm^2 to 40 mm^2. In multiple electrode embodiments, the array will usually include at least two isolated active electrodes, often at least five active electrodes, often greater than 10 active electrodes and even 50 or more active electrodes, disposed over the distal contact surfaces on the shaft. The use of small diameter active electrodes increases the electric field intensity and reduces the extent or depth of tissue heating as a consequence of the divergence of current flux lines which emanate from the exposed surface of each active electrode.

The area of the tissue treatment surface can vary widely, and the tissue treatment surface can assume a variety of geometries, with particular areas and geometries being selected for specific applications. The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) or active electrode(s) will be formed at the distal tip of the electrosurgical instrument shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical instrument shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in endoscopic procedures.

It should be clearly understood that the invention is not limited to electrically isolated active electrodes, or even to a plurality of active electrodes. For example, the array of active electrodes may be connected to a single lead that extends

centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. Applicant has found that a more conductive fluid, or one with a higher ionic concentration, will usually provide a more aggressive ablation rate. For example, a saline solution with higher levels of sodium chloride than conventional saline (which is on the order of about 0.9% sodium chloride) e.g., on the order of greater than 1% or between about 3% and 20%, may be desirable. Alternatively, the invention may be used with different types of conductive fluids that increase the power of the plasma layer by, for example, increasing the quantity of ions in the plasma, or by providing ions that have higher energy levels than sodium ions. For example, the present invention may be used with elements other than sodium, such as potassium, magnesium, calcium and other metals near the left end of the periodic chart. In addition, other electronegative elements may be used in place of chlorine, such as fluorine.

The voltage difference applied between the return electrode(s) and the active electrode(s) will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, preferably being between about 50 kHz and 500 kHz, often less than 350 kHz, and often between about 100 kHz and 200 kHz. In some applications, applicant has found that a frequency of about 100 kHz is useful because the tissue impedance is much greater at this frequency. In other applications, such as procedures in or around the heart or head and neck, higher frequencies may be desirable (e.g., 400-600 kHz) to minimize low frequency current flow into the heart or the nerves of the head and neck. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 10 volts to 500 volts, often between about 150 volts to 400 volts depending on the active electrode size, the operating frequency and the operation mode of the particular procedure or desired effect on the tissue (i.e., contraction, coagulation, cutting or ablation). Typically, the peak-to-peak voltage for ablation or cutting with a square wave form will be in the range of 10 volts to 2000 volts and preferably in the range of 100 volts to 1800 volts and more preferably in the range of about 300 volts to 1500 volts, often in the range of about 300 volts to 800 volts peak to peak (again, depending on the electrode size, number of electrons, the operating frequency and the operation mode). Lower peak-to-peak voltages will be used for tissue coagulation, thermal heating of tissue, or collagen contraction and will typically be in the range from

the target tissue, the desired tissue heating rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in U.S. Patent No. 5,697,909, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual active electrode in contact with a low resistance medium (e.g., saline irrigant or blood), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said active electrode into the low resistance medium (e.g., saline irrigant or blood).

Referring to Fig. 1, an exemplary electrosurgical system 11 for treatment of tissue in the spine will now be described in detail. Electrosurgical system 11 generally comprises an electrosurgical handpiece or probe 10 connected to a power supply 28 for providing high frequency voltage to a target site, and a fluid source 21 for supplying electrically conductive fluid 50 to probe 10. In addition, electrosurgical system 11 may include an endoscope (not shown) with a fiber optic head light for viewing the surgical site. The endoscope may be integral with probe 10, or it may be part of a separate instrument. The system 11 may also include a vacuum source (not shown) for coupling to a suction lumen or tube 211 (see Fig. 4) in the probe 10 for aspirating the target site.

As shown, probe 10 generally includes a proximal handle 19 and an elongate shaft 18 having an array 12 of active electrodes 58 at its distal end. A connecting cable 34 has a connector 26 for electrically coupling the active electrodes 58 to power supply 28. The active electrodes 58 are electrically isolated from each other and each of electrodes 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors (not shown). A fluid supply tube 15 is connected to a fluid tube 14 of probe 10 for supplying electrically conductive fluid 50 to the target site. Fluid supply tube 15 may be connected to a suitable pump (not shown), if desired.

Power supply 28 has an operator controllable voltage level adjustment 30 to change the applied voltage level, which is observable at a voltage level display 32. Power supply 28 also includes first, second and third foot pedals 37, 38, 39 and a cable 36 which is removably coupled to power supply 28. The foot pedals 37, 38, 39 allow the surgeon to remotely adjust the energy level applied to active electrodes 58. In an exemplary embodiment, first foot pedal 37 is used to place the power supply into the "ablation" mode and second foot pedal 38 places power supply 28 into the "sub-ablation"

frequency voltage of about 10 volts RMS to 500 volts RMS between one or more active electrodes (and/or coagulation electrode) and one or more return electrodes. In the exemplary embodiment, the power supply applies about 70 volts RMS to 350 volts RMS in the ablation mode and about 20 volts to 90 volts in a subablation mode, preferably 45 volts to 70 volts in the subablation mode (these values will, of course, vary depending on the probe configuration attached to the power supply and the desired mode of operation).

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from several milliwatts to tens of watts per electrode, depending on the volume of target tissue being treated, and/or the maximum allowed temperature selected for the probe tip. The power supply allows the user to select the voltage level according to the specific requirements of a particular procedure, e.g., spinal surgery, arthroscopic surgery, dermatological procedure, ophthalmic procedures, open surgery, or other endoscopic surgery procedure.

As shown in Fig. 2, the power supply generally comprises a radio frequency (RF) power oscillator 70 having output connections for coupling via a power output signal 71 to the load impedance, which is represented by the electrode assembly when the electrosurgical probe is in use. In the representative embodiment, the RF oscillator operates at about 100 kHz. The RF oscillator is not limited to this frequency and may operate at frequencies of about 300kHz to 600kHz. In particular, for cardiac applications, the RF oscillator will preferably operate in the range of about 400 kHz to about 600 kHz. The RF oscillator will generally supply a square wave signal with a crest factor of about 1 to 2. Of course, this signal may be a sine wave signal or other suitable wave signal depending on the application and other factors, such as the voltage applied, the number and geometry of the electrodes, etc. The power output signal 71 is designed to incur minimal voltage decrease (i.e., sag) under load. This improves the applied voltage to the active electrodes and the return electrode, which improves the rate of volumetric removal (ablation) of tissue.

Power is supplied to RF oscillator 70 by a switching power supply 72 coupled between the power line and the RF oscillator rather than a conventional transformer. The switching power supply 72 allows power supply 28 to achieve high peak power output without the large size and weight of a bulky transformer. The architecture of the switching power supply also has been designed to reduce electromagnetic noise such that U.S. and foreign EMI requirements are met. This architecture comprises a zero voltage switching or crossing, which causes the transistors

active electrode into the low resistance medium (e.g., saline irrigant or conductive gel). Power output signal may also be coupled to a plurality of current limiting elements 96, which are preferably located on the daughter board since the current limiting elements may vary depending on the application. A more complete description of a representative power supply can be found in commonly assigned U.S. Patent Application No. 09/058,571, previously incorporated herein by reference.

Figs. 4-6 illustrate an exemplary electrosurgical probe 20 constructed according to the principles of the present invention. As shown in Fig. 4, probe 20 generally includes an elongated shaft 100 which may be flexible or rigid, a handle 204 coupled to the proximal end of shaft 100 and an electrode support member 102 coupled to the distal end of shaft 100. Shaft 100 preferably comprises an electrically conducting material, usually metal, which is selected from the group comprising tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. In this embodiment, shaft 100 includes an electrically insulating jacket 108, which is typically formed as one or more electrically insulating sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulating jacket over the shaft prevents direct electrical contact between these metal elements and any adjacent body structure or the surgeon. Such direct electrical contact between a body structure (*e.g.*, tendon) and an exposed electrode could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis. Alternatively, the return electrode may comprise an annular band coupled to an insulating shaft and having a connector extending within the shaft to its proximal end.

Handle 204 typically comprises a plastic material that is easily molded into a suitable shape for handling by the surgeon. Handle 204 defines an inner cavity (not shown) that houses the electrical connections 250 (Fig. 6), and provides a suitable interface for connection to an electrical connecting cable distal portion 22 (see Fig. 1) Electrode support member 102 extends from the distal end of shaft 100 (usually about 1 mm to 20 mm), and provides support for a plurality of electrically isolated active electrodes 104 (see Fig. 5). As shown in Fig. 4, a fluid tube 233 extends through an opening in handle 204, and includes a connector 235 for connection to a fluid supply source, for supplying electrically conductive fluid to the target site. Depending on the configuration of the distal surface of shaft 100, fluid tube 233 may extend through a single lumen (not shown) in shaft 100, or it may be coupled to a plurality of lumens (also not shown) that extend through shaft 100 to a plurality of openings at its distal end. In the

area of the joint will be flooded with isotonic saline and the probe 90 will be introduced into this flooded target area. Electrically conductive fluid can be continually resupplied to maintain the conduction path between return electrode 112 and active electrodes 104. In other embodiments, the distal portion of probe 20 may be dipped into a source of electrically conductive fluid, such as a gel or isotonic saline, prior to positioning at the target site. Applicant has found that the surface tension of the fluid and/or the viscous nature of a gel allows the conductive fluid to remain around the active and return electrodes for long enough to complete its function according to the present invention, as described below. Alternatively, the conductive fluid, such as a gel, may be applied directly to the target site.

In alternative embodiments, the fluid path may be formed in probe 90 by, for example, an inner lumen or an annular gap between the return electrode and a tubular support member within shaft 100 (see Figs. 8A and 8B). This annular gap may be formed near the perimeter of the shaft 100 such that the electrically conductive fluid tends to flow radially inward towards the target site, or it may be formed towards the center of shaft 100 so that the fluid flows radially outward. In both of these embodiments, a fluid source (e.g., a bag of fluid elevated above the surgical site or having a pumping device), is coupled to probe 90 via a fluid supply tube (not shown) that may or may not have a controllable valve. A more complete description of an electrosurgical probe incorporating one or more fluid lumen(s) can be found in U.S. Patent No. 5,697,281, the complete disclosure of which has previously been incorporated herein by reference.

Referring to Fig. 5, the electrically isolated active electrodes 104 are spaced apart over tissue treatment surface 212 of electrode support member 102. The tissue treatment surface and individual active electrodes 104 will usually have dimensions within the ranges set forth above. In the representative embodiment, the tissue treatment surface 212 has a circular cross-sectional shape with a diameter in the range of 1 mm to 20 mm. The individual active electrodes 104 preferably extend outward from tissue treatment surface 212 by a distance of about 0.1 mm to 4 mm, usually about 0.2 mm to 2 mm. Applicant has found that this configuration increases the high electric field intensities and associated current densities around active electrodes 104 to facilitate the ablation and shrinkage of tissue as described in detail above.

In the embodiment of Figs. 4 to 6, the probe includes a single, larger opening 209 in the center of tissue treatment surface 212, and a plurality of active electrodes (e.g., about 3-15) around the perimeter of surface 212 (see Fig. 5).

embodiments, the voltage reduction element primarily allows the electrosurgical probe to be compatible with various electrosurgical generators supplied by ArthroCare Corporation (Sunnyvale, CA) that are adapted to apply higher voltages for ablation or vaporization of tissue. For thermal heating or coagulation of tissue, for example, the voltage reduction element will serve to reduce a voltage of about 100 volts rms to 170 volts rms (which is a setting of 1 or 2 on the ArthroCare Model 970 and 980 (i.e., 2000) Generators) to about 45 volts rms to 60 volts rms, which is a suitable voltage for coagulation of tissue without ablation (e.g., molecular dissociation) of the tissue.

Of course, for some procedures, the probe will typically not require a voltage reduction element. Alternatively, the probe may include a voltage increasing element or circuit, if desired. Alternatively or additionally, the cable 34 and/or cable distal end 22 that couples the power supply 28 to the probe may be used as a voltage reduction element. The cable has an inherent capacitance that can be used to reduce the power supply voltage if the cable is placed into the electrical circuit between the power supply, the active electrodes and the return electrode. In this embodiment, the cable distal end 22 may be used alone, or in combination with one of the voltage reduction elements discussed above, e.g., a capacitor. Further, it should be noted that the present invention can be used with a power supply that is adapted to apply a voltage within the selected range for treatment of tissue. In this embodiment, a voltage reduction element or circuitry may not be desired.

Figs. 8A-8C schematically illustrate the distal portion of three different embodiments of probe 90 according to the present invention. As shown in Fig. 8A, active electrodes 104 are anchored in a support matrix 102' of suitable insulating material (*e.g.*, silicone or a ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elkgrove, Illinois, because of its high thermal conductivity, good electrically insulative properties, high flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point. The support matrix 102' is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 102' and the proximal end of probe 90. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy or silicone-based material.

the distal tips of active electrodes 104 with current flow from active electrodes 104 through the target tissue to return electrode 112, the high electric field intensities causing ablation of tissue 52 in zone 88.

Fig. 8B illustrates another alternative embodiment of electrosurgical probe 90 which has a return electrode 112 positioned within tubular member 78. Return electrode 112 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 112. In this embodiment, a voltage difference is applied between active electrodes 104 and return electrode 112 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60. As a result of the applied voltage difference and concomitant high electric field intensities at the tips of active electrodes 104, tissue 52 becomes ablated or transected in zone 88.

Fig. 8C illustrates another embodiment of probe 90 that is a combination of the embodiments in Figs. 8A and 8B. As shown, this probe includes both an inner lumen 57 and an outer gap or plurality of outer lumens 54 for flow of electrically conductive fluid. In this embodiment, the return electrode 112 may be positioned within tubular member 78 as in Fig. 8B, outside of tubular member 78 as in Fig. 8A, or in both locations.

In some embodiments, the probe 20/90 will also include one or more aspiration electrode(s) coupled to the aspiration lumen for inhibiting clogging during aspiration of tissue fragments from the surgical site. As shown in Fig. 9, one or more of the active electrodes 104 may comprise loop electrodes 140 that extend across distal opening 209 of the suction lumen within shaft 100. In the representative embodiment, two of the active electrodes 104 comprise loop electrodes 140 that cross over the distal opening 209. Of course, it will be recognized that a variety of different configurations are possible, such as a single loop electrode, or multiple loop electrodes having different configurations than shown. In addition, the electrodes may have shapes other than loops, such as the coiled configurations shown in Figs. 10 and 11. Alternatively, the electrodes may be formed within suction lumen proximal to the distal opening 209, as shown in Fig. 13. The main function of loop electrodes 140 is to ablate portions of tissue that are drawn into the suction lumen to prevent clogging of the lumen.

In some embodiments, loop electrodes 140 are electrically isolated from the other active electrodes 104. In other embodiments, the loop electrodes 140 and active electrodes 104 may be electrically connected to each other such that both are activated

aspiration electrode 160 comprises a loop electrode that extends across the aspiration lumen 162. However, it will be recognized that many other configurations are possible. In this embodiment, the return electrode 164 is located towards the exterior of the shaft, as in the previously described embodiments. Alternatively, the return electrode(s) may be located within the aspiration lumen 162 with the aspiration electrode 160. For example, the inner insulating coating 163 may be exposed at portions within the lumen 162 to provide a conductive path between this exposed portion of return electrode 164 and the aspiration electrode 160. The latter embodiment has the advantage of confining the electric currents to within the aspiration lumen. In addition, in dry fields in which the conductive fluid is delivered to the target site, it is usually easier to maintain a conductive fluid path between the active and return electrodes in the latter embodiment because the conductive fluid is aspirated through the aspiration lumen 162 along with the tissue fragments.

Referring now to Figs. 14A-14C, an alternative embodiment incorporating a metal screen 610 is illustrated. As shown, metal screen 610 has a plurality of peripheral openings 612 for receiving active electrodes 104, and a plurality of inner openings 614 for allowing aspiration of fluid and tissue through an opening 609 of the aspiration lumen. As shown, screen 610 is press fitted over active electrodes 104 and then adhered to shaft 100 of probe 20/90. Similar to the mesh electrode embodiment, metal screen 610 may comprise a variety of conductive metals, such as titanium, tantalum, steel, stainless steel, tungsten, copper, gold or the like. In the representative embodiment, metal screen 610 is coupled directly to, or integral with, active electrode(s) 104. In this embodiment, the active electrode(s) 104 and the metal screen 610 are electrically coupled to each other.

Figs. 15A to 15D illustrate embodiments of an electrosurgical probe 350 specifically designed for the treatment of herniated or diseased spinal discs. Referring to Fig. 15A, probe 350 comprises an electrically conductive shaft 352, a handle 354 coupled to the proximal end of shaft 352 and an electrically insulating support member 356 at the distal end of shaft 352. Probe 350 further includes a shrink wrapped insulating sleeve 358 over shaft 352, and an exposed portion of shaft 352 that functions as the return electrode 360. In the representative embodiment, probe 350 comprises a plurality of active electrodes 362 extending from the distal end of support member 356. As shown, return electrode 360 is spaced a further distance from active electrodes 362 than in the embodiments described above. In this embodiment, the return electrode 360 is spaced a distance of about 2.0 mm to 50 mm, preferably about 5 mm to 25 mm from active

more active electrode(s) 362 and a proximally spaced return electrode 360 as in previous embodiments. Return electrode 360 is typically spaced about 0.5 mm to 25 mm, preferably 1.0 mm to 5.0 mm from the active electrode(s) 362, and has an exposed length of about 1 mm to 20 mm. In addition, electrode assembly 372 includes two additional electrodes 374, 376 spaced axially on either side of return electrode 360. Electrodes 374, 376 are typically spaced about 0.5 mm to 25 mm, preferably about 1 mm to 5 mm from return electrode 360. In the representative embodiment, the additional electrodes 374, 376 are exposed portions of shaft 352, and the return electrode 360 is electrically insulated from shaft 352 such that a voltage difference may be applied between electrodes 374, 376 and electrode 360. In this embodiment, probe 350 may be used in at least two different modes, an ablation mode and a subablation or thermal heating mode. In the ablation mode, voltage is applied between active electrode(s) 362 and return electrode 360 in the presence of electrically conductive fluid, as described above. In the ablation mode, electrodes 374, 376 are deactivated. In the thermal heating or coagulation mode, active electrode(s) 362 are deactivated and a voltage difference is applied between electrodes 374, 376 and electrode 360 such that a high frequency current 370 flows therebetween, as shown in Fig. 15B. In the thermal heating mode, a lower voltage is typically applied below the threshold for plasma formation and ablation, but sufficient to cause some thermal damage to the tissue immediately surrounding the electrodes without vaporizing or otherwise debulking this tissue so that the current 370 provides thermal heating and/or coagulation of tissue surrounding electrodes 360, 372, 374.

Fig. 15C illustrates another embodiment of probe 350 incorporating an electrode assembly 372 having one or more active electrode(s) 362 and a proximally spaced return electrode 360 as in previous embodiments. Return electrode 360 is typically spaced about 0.5 mm to 25 mm, preferably 1.0 mm to 5.0 mm from the active electrode(s) 362, and has an exposed length of about 1 mm to 20 mm. In addition, electrode assembly 372 includes a second active electrode 380 separated from return electrode 360 by an electrically insulating spacer 382. In this embodiment, handle 354 includes a switch 384 for toggling probe 350 between at least two different modes, an ablation mode and a subablation or thermal heating mode. In the ablation mode, voltage is applied between active electrode(s) 362 and return electrode 360 in the presence of electrically conductive fluid, as described above. In the ablation mode, electrode 380 is deactivated. In the thermal heating or coagulation mode, active electrode(s) 362 may be deactivated and a voltage difference is applied between electrode 380 and electrode 360

allows the power supply 28 to, in effect, apply two different voltages simultaneously to two different electrodes. Thus, for channeling through tissue, the operator may apply a voltage sufficient to provide ablation of the tissue at the tip of the probe (i.e., tissue adjacent to the active electrode 362). At the same time, the voltage applied to the coagulation electrode 380 will be insufficient to ablate tissue. For thermal heating or coagulation of tissue, for example, the voltage reduction element will serve to reduce a voltage of about 100 volts rms to 300 volts rms to about 45 volts rms to 90 volts rms, which is a suitable voltage for coagulation of tissue without ablation (e.g., molecular dissociation) of the tissue.

In the representative embodiment, the voltage reduction element comprises a pair of capacitors forming a bridge divider(not shown) coupled to the power supply and coagulation electrode 380. The capacitors usually have a capacitance of about 200 pF to 500 pF (at 500 volts) and preferably about 300 pF to 350 pF (at 500 volts). Of course, the capacitors may be located in other places within the system, such as in, or distributed along the length of, the cable, the generator, the connector, etc. In addition, it will be recognized that other voltage reduction elements, such as diodes, transistors, inductors, resistors, capacitors or combinations thereof, may be used in conjunction with the present invention. For example, the probe 350 may include a coded resistor (not shown) that is constructed to lower the voltage applied between the return and coagulation electrodes 360, 380, respectively. In addition, electrical circuits may be employed for this purpose.

Of course, for some procedures, the probe will typically not require a voltage reduction element. Alternatively, the probe may include a voltage increasing element or circuit, if desired. Alternatively or additionally, cable 22/34 that couples power supply 28 to the probe 90 may be used as a voltage reduction element. The cable has an inherent capacitance that can be used to reduce the power supply voltage if the cable is placed into the electrical circuit between the power supply, the active electrodes and the return electrode. In this embodiment, cable 22/34 may be used alone, or in combination with one of the voltage reduction elements discussed above, e.g., a capacitor. Further, it should be noted that the present invention can be used with a power supply that is adapted to apply two different voltages within the selected range for treatment of tissue. In this embodiment, a voltage reduction element or circuitry may not be desired.

In one specific embodiment, the probe 350 is manufactured by first inserting an electrode wire (active electrode 362) through a ceramic tube (insulating member 356) such that a distal portion of the wire extends through the distal portion of

current will heat the tissue immediately surrounding the channel to coagulate any severed vessels at the surface of the channel. If the physician desires, the instrument may be held within the channel for a period of time to create a lesion around the channel, as discussed in more detail below.

Fig. 16 illustrates yet another embodiment of an electrosurgical system 440 incorporating a dispersive return pad 450 attached to the electrosurgical probe 400. In this embodiment, the invention functions in the bipolar mode as described above. In addition, the system 440 may function in a monopolar mode in which a high frequency voltage difference is applied between the active electrode(s) 410, and the dispersive return pad 450. In the exemplary embodiment, the pad 450 and the probe 400 are coupled together, and are both disposable, single-use items. The pad 450 includes an electrical connector 452 that extends into handle 404 of probe 400 for direct connection to the power supply. Of course, the invention would also be operable with a standard return pad that connects directly to the power supply. In this embodiment, the power supply 460 will include a switch, e.g., a foot pedal 462, for switching between the monopolar and bipolar modes. In the bipolar mode, the return path on the power supply is coupled to return electrode 408 on probe 400, as described above. In the monopolar mode, the return path on the power supply is coupled to connector 452 of pad 450, active electrode(s) 410 are decoupled from the electrical circuit, and return electrode 408 functions as the active electrode. This allows the surgeon to switch between bipolar and monopolar modes during, or prior to, the surgical procedure. In some cases, it may be desirable to operate in the monopolar mode to provide deeper current penetration and, thus, a greater thermal heating of the tissue surrounding the return electrodes. In other cases, such as ablation of tissue, the bipolar modality may be preferable to limit the current penetration to the tissue.

In one configuration, the dispersive return pad 450 is adapted for coupling to an external surface of the patient in a region substantially close to the target region. For example, during the treatment of tissue in the head and neck, the dispersive return pad is designed and constructed for placement in or around the patient's shoulder, upper back or upper chest region. This design limits the current path through the patient's body to the head and neck area, which minimizes the damage that may be generated by unwanted current paths in the patient's body, particularly by limiting current flow through the patient's heart. The return pad is also designed to minimize the current densities at the pad, to thereby minimize patient skin burns in the region where the pad is attached.

pump or flow regulator may be used to precisely control the flow rate of the conductive fluid.

System 400 can further include an aspiration or vacuum system (not shown) to aspirate liquids and gases from the target site. The aspiration system will usually comprise a source of vacuum coupled to fitment 614 by a aspiration connector 605.

The present invention is particularly useful in microendoscopic discectomy procedures, e.g., for decompressing a nerve root with a lumbar discectomy. As shown in Figs. 18-23, a percutaneous penetration 270 is made in the patients' back 272 so that the superior lamina 274 can be accessed. Typically, a small needle (not shown) is used initially to localize the disc space level, and a guidewire (not shown) is inserted and advanced under lateral fluoroscopy to the inferior edge of the lamina 274. Sequential cannulated dilators 276 are inserted over the guide wire and each other to provide a hole from the incision 220 to the lamina 274. The first dilator may be used to "palpate" the lamina 274, assuring proper location of its tip between the spinous process and facet complex just above the inferior edge of the lamina 274. As shown in Fig. 21, a tubular retractor 278 is then passed over the largest dilator down to the lamina 274. The dilators 276 are removed, establishing an operating corridor within the tubular retractor 278.

As shown in Fig. 19, an endoscope 280 is then inserted into the tubular retractor 278 and a ring clamp 282 is used to secure the endoscope 280. Typically, the formation of the operating corridor within retractor 278 requires the removal of soft tissue, muscle or other types of tissue that were forced into this corridor as the dilators 276 and retractor 278 were advanced down to the lamina 274. This tissue is usually removed with mechanical instruments, such as pituitary rongeurs, curettes, graspers, cutters, drills, microdebriders, and the like. Unfortunately, these mechanical instruments greatly lengthen and increase the complexity of the procedure. In addition, these instruments sever blood vessels within this tissue, usually causing profuse bleeding that obstructs the surgeon's view of the target site.

According to another aspect of the present invention, an electrosurgical probe or catheter 284 as described above is introduced into the operating corridor within the retractor 278 to remove the soft tissue, muscle and other obstructions from this corridor so that the surgeon can easily access and visualization the lamina 274. Once the surgeon has introduced the probe 284, electrically conductive fluid 285 can be delivered through tube 233 and opening 237 to the tissue (see Fig. 4). The fluid flows past the

Referring now to Figs. 20 and 21, once the operating corridor is sufficiently cleared, a laminotomy and medial facetectomy is accomplished either with conventional techniques (e.g., Kerrison punch or a high speed drill) or with the electrosurgical probe 284 as discussed above. After the nerve root is identified, medical retraction can be achieved with a retractor 288, or the present invention can be used to precisely ablate the disc. If necessary, epidural veins are cauterized either automatically or with the coagulation mode of the present invention. If an annulotomy is necessary, it can be accomplished with a microknife or the ablation mechanism of the present invention while protecting the nerve root with the retractor 288. The herniated disc 290 is then removed with a pituitary rongeur in a standard fashion, or once again through ablation as described above.

In another embodiment, the present invention involves a channeling technique in which voids or channels are formed within the disc 290, and thermal energy is applied to the tissue surface immediately surrounding these voids or channels to cause thermal damage to the tissue surface, thereby stiffening and debulking the surrounding tissue structure of the disc. Applicant has discovered that such stiffening of the tissue structure in the disc helps to reduce the pressure applied against the spinal nerves by the disc, thereby relieving back and neck pain.

As shown in Fig. 21, the electrosurgical instrument 350 is introduced to the target site at the disc 290 as described above, or in another percutaneous manner (see Figs. 23-25 below). The electrode assembly 351 is positioned adjacent to or against the disc surface, and electrically conductive fluid is delivered to the target site, as described above. Alternatively, the conductive fluid is applied to the target site, or the distal end of probe 350 is dipped into conductive fluid or gel prior to introducing the probe 350 into the patient. The power supply 28 is then activated and adjusted such that a high frequency voltage difference is applied to the electrode assembly as described above.

Depending on the procedure, the surgeon may translate or otherwise move the electrodes relative to the target disc tissue to form one or more voids, holes, channels, stripes, divots, craters, or the like within the disc. In addition, the surgeon may purposely create some thermal damage within these holes, or channels to form scar tissue that will stiffen and debulk the disc. In one embodiment, the physician axially translates the electrode assembly 351 into the disc tissue as the tissue is volumetrically removed to form one or more holes 702 therein (see also Fig. 22). The holes 702 will typically have a diameter of less than 2 mm, preferably less than 1 mm. In another embodiment (not

contact with, or adjacent to, tissue, electric current 755 flows through the tissue surrounding hole 702 and creates thermal damage therein. The coagulation and return electrodes 380, 360 both have relatively large, smooth exposed surfaces to minimize high current densities at their surfaces, which minimizes damage to the surface 705 of hole. Meanwhile, the size and spacing of these electrodes 360, 380 allows for relatively deep current penetration into the tissue 704. In the representative embodiment, the thermal necrosis (not shown) will extend about 1.0 mm to 5.0 mm from surface 705 of hole 702. In this embodiment, the probe may include one or more temperature sensors (not shown) on probe coupled to one or more temperature displays on the power supply 28 such that the physician is aware of the temperature within the hole 702 during the procedure.

In other embodiments, the physician switches the electrosurgical system from the ablation mode to the subablation or thermal heating mode after the hole 702 has been formed. This is typically accomplished by pressing a switch or foot pedal to reduce the voltage applied to a level below the threshold required for ablation for the particular electrode configuration and the conductive fluid being used in the procedure (as described above). In the subablation mode, the physician will then remove the distal end of the probe 350 from the hole 702. As the probe is withdrawn, high frequency current flows from the active electrodes 362 through the surrounding tissue to the return electrode 360. This current flow heats the tissue and coagulates severed blood vessels at surface 705.

In another embodiment, the electrosurgical probe of the present invention can be used to ablate and/or contract soft tissue within the disc 290 to allow the annulus fibrosus 292 to repair itself to prevent reoccurrence of this procedure. For tissue contraction, a sufficient voltage difference is applied between the active electrodes 104 and the return electrode 112 to elevate the tissue temperature from normal body temperatures (e.g., 37°C) to temperatures in the range of 45°C to 90°C, preferably in the range from 60°C to 70°C. This temperature elevation causes contraction of the collagen connective fibers within the disc tissue so that the nucleus pulposus withdraws into the annulus fibrosus 292.

In one method of tissue contraction according to the present invention, an electrically conductive fluid is delivered to the target site as described above, and heated to a sufficient temperature to induce contraction or shrinkage of the collagen fibers in the target tissue. The electrically conductive fluid is heated to a temperature sufficient to substantially irreversibly contract the collagen fibers, which generally requires a tissue temperature in the range of about 45°C to 90°C, usually about 60°C to 70°C. The fluid is

PCT/US94/05168, the depth of current penetration into tissue increases with increasing dimensions of an individual active electrode (assuming other factors remain constant, such as the frequency of the electric current, the return electrode configuration, etc.). The depth of current penetration (which refers to the depth at which the current density is sufficient to effect a change in the tissue, such as collagen shrinkage, irreversible necrosis, etc.) is on the order of the active electrode diameter for the bipolar configuration of the present invention and operating at a frequency of about 100kHz to about 200kHz. Accordingly, for applications requiring a smaller depth of current penetration, one or more active electrodes of smaller dimensions would be selected. Conversely, for applications requiring a greater depth of current penetration, one or more active electrodes of larger dimensions would be selected.

Figs. 23-25 illustrate another system and method for treating swollen or herniated spinal discs according to the present invention. In this procedure, an electrosurgical probe 800 comprises a long, thin needle-like shaft 802 (e.g., on the order of about 1 mm in diameter or less) that can be percutaneously introduced posteriorly through the patient's back directly into the spine. The shaft 802 may or may not be flexible, depending on the method of access chosen by the physician. The probe shaft 802 will include one or more active electrode(s) 804 for applying electrical energy to tissues within the spine. The probe 800 may include one or more return electrode(s) 806, or the return electrode may be positioned on the patient's back, as a dispersive pad (not shown). As discussed below, however, a bipolar design is preferable.

As shown in Fig. 23, the distal portion of shaft 802 is introduced anteriorly through a small percutaneous penetration into the annulus fibrosus 292 of the target spinal disc. To facilitate this process, the distal end of shaft 802 may taper down to a sharper point (e.g., a needle), which can then be retracted to expose active electrode(s) 804. Alternatively, the electrodes may be formed around the surface of the tapered distal portion of shaft (not shown). In either embodiment, the distal end of shaft is delivered through the annulus 292 to the target nucleus pulposus 294, which may be herniated, extruded, non-extruded, or simply swollen. As shown in Fig. 24, high frequency voltage is applied between active electrode(s) 804 and return electrode(s) 806 to heat the surrounding collagen to suitable temperatures for contraction (i.e., typically about 55°C to about 70°C). As discussed above, this procedure may be accomplished with a monopolar configuration, as well. However, applicant has found that the bipolar configuration

is disturbed. In one embodiment, shield 922 may be coated with a durable, hard compound such as titanium nitride. Such a coating has the advantage of providing reduced friction between shield 922 and introducer inner wall 932 as shaft 902 is axially translated within introducer needle 928 (e.g., Figs. 31A, 31B).

Fig. 27A is a side view of an electrosurgical probe 900 showing a first curve 924 and a second curve 926 located at distal end portion 902a, wherein second curve 926 is proximal to first curve 924. First curve 924 and second curve 926 may be separated by a linear (i.e. straight, or non-curved), or substantially linear, inter-curve portion 925 of shaft 902.

Fig. 27B is a side view of shaft distal end portion 902a within a representative introducer device or needle 928 having an inner diameter D. Shaft distal end portion 902a includes first curve 924 and second curve 926 separated by inter-curve portion 925. In one embodiment, shaft distal end portion 902a includes a linear or substantially linear proximal portion 901 extending from proximal end portion 902b to second curve 926, a linear or substantially linear inter-curve portion 925 between first and second curves 924, 926, and a linear or substantially linear distal portion 909 between first curve 924 and the distal tip of shaft 902 (the distal tip is represented in Fig. 27B as an electrode head 911). When shaft distal end portion 902a is located within introducer needle 928, first curve 924 subtends a first angle $\forall$ to the inner surface of needle 928, and second curve 926 subtends a second angle $\exists$ to inner surface 932 of needle 928. (In the situation shown in Fig. 27B, needle inner surface 932 is essentially parallel to the longitudinal axis of shaft proximal end portion 902b (Fig. 27A).) In one embodiment, shaft distal end portion 902a is designed such that the shaft distal tip occupies a substantially central transverse location within the lumen of introducer needle 928 when shaft distal end portion 902a is translated axially with respect to introducer needle 928. Thus, as shaft distal end portion 902a is advanced through the distal opening of needle 928 (Figs. 30B, 31B), and then retracted back into the distal opening, the shaft distal tip will always occupy a transverse location towards the center of introducer needle 928 (even though the tip may be curved or biased away from the longitudinal axis of shaft 902 and needle 928 upon its advancement past the distal opening of introducer needle 928). In one embodiment, shaft distal end portion 902a is flexible and has a configuration which requires shaft distal end portion 902a be distorted in the region of at least second curve 926 by application of a lateral force imposed by inner wall 932 of introducer needle 928

end portion 902a is advanced out through the distal opening of introducer needle 928, as compared with the corresponding angle when shaft distal end portion is completely retracted within introducer needle 928. For example, Fig. 27C shows shaft 902 of Fig. 27B free from introducer needle 928, wherein first and second curves 924, 926 are allowed to adopt their natural or uncompressed angles ∀' and ∃', respectively, wherein ∃' is typically equal to or greater than ∃. Angle ∀' may be greater than, equal to, or less than angle ∀. Angle ∃' is subtended by inter-curve portion 925 and proximal portion 901. When shaft distal end portion 902a is unrestrained by introducer needle 928, proximal portion 901 approximates the longitudinal axis of shaft 902. Angle ∀' is subtended between linear distal portion 909 and a line drawn parallel to proximal portion 901. Electrode head 911 is omitted from Fig. 27C for the sake of clarity.

The principle described above with reference to shaft 902 and introducer needle 928 may equally apply to a range of other medical devices. That is to say, the "S-curve" configuration of the invention may be included as a feature of any medical system or apparatus in which a medical instrument may be axially translated or passed within an introducer device. In particular, the principle of the "S-curve" configuration of the invention may be applied to any apparatus wherein it is desired that the distal end of the medical instrument does not contact or impinge upon the introducer device as the medical instrument is advanced from or retracted into the introducer device. The introducer device may be any apparatus through which a medical instrument is passed. Such medical systems may include, for example, a catheter, a cannula, an endoscope, and the like.

When shaft 902 is advanced distally through the needle lumen to a point where second curve 926 is located distal to needle distal end 928a, the shaft distal tip is deflected from the longitudinal axis of needle 928. The amount of this deflection is determined by the relative size of angles ∃' and ∀', and the relative lengths of L1 and L2. The amount of this deflection will in turn determine the size of a channel or lesion (depending on the application) formed in a tissue treated by electrode head 911 when shaft 902 is rotated circumferentially with respect to the longitudinal axis of probe 900.

As a result of the pre-defined bias in shaft 902, shaft distal end portion 902a will contact a larger volume of tissue than a linear shaft having the same dimensions. In addition, in one embodiment the pre-defined bias of shaft 902 allows the physician to guide or steer the distal tip of shaft 902 by a combination of axial movement

provides an additional advantage, in that the sharp edges of cusp 911b, and more particularly of apical spike 911a, facilitate movement and guiding of head 911 into tissue during surgical procedures, as described fully hereinbelow. In contrast, an electrosurgical probe having a blunt or rounded apical electrode is more likely to follow a path of least resistance, such as a channel which was previously ablated within nucleus pulposus tissue. Although certain embodiments of the invention depict head 911 as having a single apical spike, other shapes for the apical portion of active electrode 910 are also within the scope of the invention.

Fig. 28B is a longitudinal cross-sectional view of distal end portion 902a of shaft 902. Apical electrode head 911 is in communication with a filament 912. Filament 912 typically comprises an electrically conductive wire encased within a first insulating sleeve 914. First insulating sleeve 914 comprises an insulator, such as various synthetic polymeric materials. An exemplary material from which first insulating sleeve 914 may be constructed is a polyimide. First insulating sleeve 914 may extend the entire length of shaft 902 proximal to head 911. An insulating collar or spacer 916 is disposed on the distal end of first insulating sleeve 914, adjacent to electrode head 911. Collar 916 preferably comprises a material such as a glass, a ceramic, or silicone. The exposed portion of first insulating sleeve 914 (i.e., the portion proximal to collar 916) is encased within a cylindrical return electrode 918. Return electrode 918 may extend proximally the entire length of shaft 902. Return electrode 918 may comprise an electrically conductive material such as stainless steel, tungsten, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, nickel or its alloys, and the like. A proximal portion of return electrode 918 is encased within a second insulating sleeve 920, so as to provide an exposed band of return electrode 918 located distal to second sleeve 920 and proximal to collar 916. Second sleeve 920 provides an insulated portion of shaft 920 which facilitates handling of probe 900 by the surgeon during a surgical procedure. A proximal portion of second sleeve 920 is encased within an electrically conductive shield 922. Second sleeve 920 and shield 922 may also extend proximally for the entire length of shaft 902.

Fig. 29 is a side view of shaft distal end portion 902a of electrosurgical probe 900, indicating the position of first and second curves 924, 926, respectively. Probe 900 includes head 911, collar 916, return electrode 918, second insulating sleeve 920, and shield 922, generally as described with reference to Figs. 28A, 28B. In the embodiment of Fig. 29, first curve 924 is located within return electrode 918, while second curve 926 is located within shield 922. However, according to various

Fig. 32A). In other embodiments, other numbers and arrangements of depth markings 903 may be included on shaft 902. For example, in certain embodiments, depth markings may be present along the entire length of shield 922, or a single depth marking 903 may be present at shaft proximal end portion 902b. Depth markings serve to indicate to the surgeon the depth of penetration of shaft 902 into a patient's tissue, organ, or body, during a surgical procedure. Depth markings 903 may be formed directly in or on shield 922, and may comprise the same material as shield 922. Alternatively, depth markings 903 may be formed from a material other than that of shield 922. For example, depth markings may be formed from materials which have a different color and/or a different level of radiopacity, as compared with material of shield 922. For example, depth markings may comprise a metal, such as tungsten, gold, or platinum oxide (black), having a level of radiopacity different from that of shield 922. Such depth markings may be visualized by the surgeon during a procedure performed under fluoroscopy. In one embodiment, the length of the introducer needle and the shaft 902 are selected to limit the range of the shaft beyond the distal tip of the introducer needle.

Fig. 32B shows a probe 900, wherein shaft 902 includes a mechanical stop 905. Preferably, mechanical stop 905 is located at shaft proximal end portion 902b. Mechanical stop 905 limits the distance to which shaft distal end 902a can be advanced through introducer 928 by making mechanical contact with a proximal end 928b of introducer 928. Mechanical stop 905 may be a rigid material or structure affixed to, or integral with, shaft 902. Mechanical stop 905 also serves to monitor the depth or distance of advancement of shaft distal end 902a through introducer 928, and the degree of penetration of distal end 902a into a patient's tissue, organ, or body. In one embodiment, mechanical stop 905 is movable on shaft 902, and stop 905 includes a stop adjustment unit 907 for adjusting the position of stop 905 and for locking stop 905 at a selected location on shaft 902.

Fig. 33 illustrates stages in manufacture of an active electrode 910 of a shaft 902, according to one embodiment of the present invention. Stage 33-I shows an elongated piece of electrically conductive material 912', e.g., a metal wire, as is well known in the art. Material 912' includes a first end 912'a and a second end 912'b. . Stage 33-II shows the formation of a globular structure 911' from first end 912'a, wherein globular structure 911' is attached to filament 912. Globular structure 911' may be conveniently formed by applying heat to first end 912'a. Techniques for applying heat to the end of a metal wire are well known in the art. Stage 33-III shows the formation of an

portion of the second insulating sleeve within a shield of electrically conductive material, such as a cylinder of stainless steel or other metal, as previously described herein.

Fig. 35 schematically represents a series of steps involved in a method of making an electrosurgical probe of the present invention, wherein step 1100 involves providing a shaft having at least one active electrode and at least one return electrode. An exemplary shaft to be provided in step 1100 is that prepared according to the method described hereinabove with reference to Fig. 34, i.e., the shaft includes a first curve. Step 1102 involves bending the shaft to form a second curve. Preferably, the second curve is located at the distal end portion of the shaft, but proximal to the first curve. In one embodiment, the second curve is greater than the first curve. (Features of both the first curve and second curve have been described hereinabove, e.g., with reference to Fig 27B.) Step 1104 involves providing a handle for the probe. The handle includes a connection block for electrically coupling the electrodes thereto. Step 1106 involves coupling the active and return electrodes of the shaft to the connection block. The connection block allows for convenient coupling of the electrosurgical probe to a power supply (e.g., power supply 28, Fig. 1). Thereafter, step 1108 involves affixing the shaft to the handle.

Fig. 36A schematically represents a normal intervertebral disc 290 in relation to the spinal cord 720, the intervertebral disc having an outer annulus fibrosus 292 enclosing an inner nucleus pulposus 294. The nucleus pulposus is a relatively soft tissue comprising proteins and having a relatively high water content, as compared with the harder, more fibrous annulus fibrosus. Figs. 36B-D each schematically represent an intervertebral disc having a disorder which can lead to discogenic pain, for example due to compression of a nerve root by a distorted annulus fibrosus. Thus, Fig. 36B schematically represents an intervertebral disc exhibiting a protrusion of the nucleus pulposus and a concomitant distortion of the annulus fibrosus. The condition depicted in Fig. 36B clearly represents a contained herniation, which can result in severe and often debilitating pain. Fig. 36C schematically represents an intervertebral disc exhibiting a plurality of fissures within the annulus fibrosus, again with concomitant distortion of the annulus fibrosus. Such annular fissures may be caused by excessive pressure exerted by the nucleus pulposus on the annulus fibrosus. Excessive pressure within the nucleus pulposus tends to intensify disc disorders associated with the presence of such fissures. Fig. 36D schematically represents an intervertebral disc exhibiting fragmentation of the nucleus pulposus and a concomitant distortion of the annulus fibrosus. In this situation,

Shaft 902 includes an active electrode 910, as described hereinabove. Shaft 902 features curvature at distal end 902a/902'a, for example, as described with reference to Figs. 27A-B. By rotating shaft 902 through approximately 180°, shaft distal end 902a can be moved to a position indicated by the dashed lines and labeled as 902'a. Thereafter, rotation of shaft 902 through an additional 180° defines a substantially cylindrical three-dimensional space with a proximal conical area represented as a hatched area (shown between 902a and 902'a). The bi-directional arrow distal to active electrode 910 indicates translation of shaft 902 substantially along the longitudinal axis of shaft 902. By a combination of axial and rotational movement of shaft 902, a much larger volume of the nucleus pulposus can be contacted by electrode 910, as compared with a corresponding probe having a linear (non-curved) shaft. Furthermore, the curved nature of shaft 902 allows the surgeon to change the direction of advancement of shaft 902 by appropriate rotation thereof, and to guide shaft distal end 902a to a particular target site within the nucleus pulposus.

It is to be understood that according to certain embodiments of the invention, the curvature of shaft 902 is the same, or substantially the same, both prior to it being used in a surgical procedure and while it is performing ablation during a procedure, e.g., within an intervertebral disc. (One apparent exception to this statement, relates to the stage in a procedure wherein shaft 902 may be transiently "molded" into a somewhat more linear configuration by the constraints of introducer inner wall 932 during housing, or passing, of shaft 902 within introducer 928.) In contrast, certain prior art devices, and embodiments of the invention to be described hereinbelow (e.g., with reference to Fig. 43A, 43B), may be linear or lacking a naturally defined configuration prior to use, and then be steered into a selected configuration during a surgical procedure.

While shaft distal end 902a is at or adjacent to a target site within the nucleus pulposus, probe 900 may be used to ablate tissue by application of a first high frequency voltage between active electrode 910 and return electrode 918 (e.g., Fig. 26B), wherein the volume of the nucleus pulposus is decreased, the pressure exerted by the nucleus pulposus on the annulus fibrosus is decreased, and at least one nerve or nerve root is decompressed. Accordingly, discogenic pain experienced by the patient may be alleviated. According to one aspect of the invention, application of the first high frequency voltage results in formation of a plasma in the vicinity of active electrode 910, and the plasma causes ablation by breaking down high molecular weight disc tissue components (e.g., proteins) into low molecular weight gaseous materials. Such low

disc. In the situation depicted in Fig. 38, the target site is occupied by an errant fragment 294' of nucleus pulposus tissue. Shaft distal end 902 may be guided or directed, at least in part, by appropriate placement of introducer 928, such that active electrode 910 is in the vicinity of fragment 294'. Preferably, active electrode 910 is adjacent to, or in contact with, fragment 294'. Although Fig. 38 depicts a disc in which a fragment of nucleus pulposus is targeted by shaft 902, the invention described with reference to Fig. 38 may also be used for targeting other aberrant structures within an intervertebral disc, including annular fissures and contained herniations. In one embodiment, shaft 902 includes at least one curve (not shown in Fig. 38), and other features described herein with reference to Figs. 26A-35, wherein shaft distal end 902a may be precisely guided to a target site within an intervertebral disc, e.g., by an appropriate combination of axial and rotational movement of shaft 902. The procedure illustrated in Fig. 38 may be performed generally according to the description presented with reference to Fig. 37. That is, shaft 902 is introduced into the disc via introducer 928 in a percutaneous procedure. After shaft distal end 902a has been guided to a target site, tissue at or adjacent to that site is ablated by application of a first high frequency voltage. Thereafter, depending on the particular condition of the disc being treated, a second high frequency voltage may optionally be applied in order to locally coagulate tissue within the disc.

Fig. 39 schematically represents a series of steps involved in a method of ablating disc tissue according to the present invention; wherein step 1200 involves advancing an introducer needle towards an intervertebral disc to be treated. The introducer needle has a lumen having a diameter greater than the diameter of the shaft distal end, thereby allowing passage of the shaft distal end through the lumen of the introducer needle. In one embodiment, the introducer needle typically has a length in the range of from about 3 cm to about 25 cm, and the lumen of the introducer needle typically has a diameter in the range of from about 0.5 cm. to about 2.5 mm. Typically, the lumen of the introducer needle has a diameter in the range of from about 105% to about 500% of the diameter of the shaft distal end. The introducer needle may be inserted in the intervertebral disc percutaneously, e.g. via a posterior lateral approach. In one embodiment, the introducer needle may have dimensions similar to those of an epidural needle, the latter well known in the art.

Optional step 1202 involves introducing an electrically conductive fluid, such as saline, into the disc. In one embodiment, *in lieu* of step 1202, the ablation procedure may rely on the electrical conductivity of the nucleus pulposus itself. Step

longitudinal axis, or may be moved by a combination of axial and rotational movement. In the latter case, a substantially spiral path is defined by the shaft distal end. After step 1210, steps 1206 and 1208 may be repeated with respect to the fresh tissue of the nucleus pulposus contacted by the shaft distal end. Alternatively, after step 1206 or step 1208, the shaft may be withdrawn from the disc (step 1212). Step 1214 involves withdrawing the introducer needle from the disc. In one embodiment, the shaft and the needle may be withdrawn from the disc concurrently. Withdrawal of the shaft from the disc may facilitate exhaustion of ablation by-products from the disc. Such ablation by-products include low molecular weight gaseous compounds derived from molecular dissociation of disc tissue components, as described hereinabove. The above method may be used to treat any disc disorder in which Coblation® and or coagulation of disc tissue is indicated, including contained herniations.

In one embodiment, an introducer needle may be introduced generally as described for step 1200 (Fig. 39), and a fluoroscopic fluid may be introduced into the disc for the purpose of visualizing and diagnosing a disc abnormality or disorder. Thereafter, depending on the diagnosis, a treatment procedure may be performed, e.g., according to steps 1202 through 1214, using the same introducer needle as access. In one embodiment, a distal portion, or the entire length, of the introducer needle may have an insulating coating on its external surface. Such an insulating coating on the introducer needle may prevent interference between the electrically conductive introducer needle and electrode(s) on the probe.

The size or volume of the void or channel formed in a tissue by a single straight pass of the shaft through the tissue to be ablated is a function of the diameter of the shaft (e.g., the diameter of the shaft distal end and active electrode) and the amount of axial translation of the shaft. (By a "single straight pass" of the shaft is meant one axial translation of the shaft in a distal direction through the tissue, in the absence of rotation of the shaft about the longitudinal axis of the shaft, with the power from the power supply turned on.) In the case of a curved shaft, according to various embodiments of the instant invention, a larger channel can be formed by rotating the shaft as it is advanced through the tissue. The size of a channel formed in a tissue by a single rotational pass of the shaft through the tissue to be ablated is a function of the deflection of the shaft, and the amount of rotation of the shaft about its longitudinal axis, as well as the diameter of the shaft (e.g., the diameter of the shaft distal end and active electrode) and the amount of axial translation of the shaft. (By a "single rotational pass" of the shaft is meant one axial

abnormality, e.g., via X-ray examination, endoscopically, or fluoroscopically. As an example, a defined target site within a disc may comprise a fragment of the nucleus pulposus that has migrated into the annulus fibrosus (see, e.g., Fig. 36D) resulting in discogenic pain. However, guiding the shaft to defined sites associated with other types of disc disorders are also possible and is within the scope of the invention.

Guiding the shaft distal end to the defined target site may be performed by axial and/or rotational movement of a curved shaft, as described hereinabove. Or the shaft may be steerable, for example, by means of a guide wire, as is well known in the art. Guiding the shaft distal end may be performed during visualization of the location of the shaft relative to the disc, wherein the visualization may be performed endoscopically or via fluoroscopy. Endoscopic examination may employ a fiber optic cable (not shown). The fiber optic cable may be integral with the electrosurgical probe, or be part of a separate instrument (endoscope). Step 1306 involves ablating disc tissue, and is analogous to step 1206 (Fig. 39). Before or during step 1306, an electrically conductive fluid may be applied to the disc tissue and/or the shaft in order to provide a path for current flow between active and return electrodes on the shaft, and to facilitate and/or maintain a plasma in the vicinity of the distal end portion of the shaft. After the shaft distal end has been guided to a target site and tissue at that site has been ablated, the shaft may be moved locally, e.g., within the same region of the nucleus pulposus, or to a second defined target site within the same disc. The shaft distal end may be moved as described herein (e.g., with reference to step 1210, Fig. 39). Or, according to an alternative embodiment, the shaft may be steerable, e.g., by techniques well known in the art. Steps 1310 and 1312 are analogous to steps 1212 and 1214, respectively (described with reference to Fig. 39).

It is known in the art that epidural steroid injections can transiently diminish perineural inflammation of an affected nerve root, leading to alleviation of discogenic pain. In one embodiment of the invention, methods for ablation of disc tissue described hereinabove may be conveniently performed in conjunction with an epidural steroid injection. For example, ablation of disc tissue and epidural injection could be carried out as part of a single procedure, by the same surgeon, using equipment common to both procedures (e.g. visualization equipment). Combining Coblation® and epidural injection in a single procedure may provide substantial cost-savings to the healthcare industry, as well as a significant improvement in patient care.

probe 900' can be kept to a minimum. Furthermore, when the fluid delivery assembly is positioned within ancillary introducer 938, electrically conductive fluid can be conveniently replenished to the interior of the disc at any given time during the procedure. Nevertheless, in other embodiments, the fluid delivery assembly can be physically coupled to electrosurgical probe 900'.

In some methods, a radiopaque contrast solution (not shown) may be delivered through a fluid delivery assembly so as to allow the surgeon to visualize the intervertebral disc under fluoroscopy. In some configurations, a tracking device 942 can be positioned on shaft distal end portion 902"a. Additionally or alternatively, shaft 902" can be marked incrementally, e.g., with depth markings 903a-f (Fig. 32A), to indicate to the surgeon how far the active electrode is advanced into the intervertebral disc. In one embodiment, tracking device 942 includes a radiopaque material that can be visualized under fluoroscopy. Such a tracking device 942 and depth markings 903a-f provide the surgeon with means to track the position of the active electrode 910 relative to a specific target site within the disc to which active electrode 910 is to be guided. Such specific target sites may include, for example, an annular fissure, a contained herniation, or a fragment of nucleus pulposus. The surgeon can determine the position of the active electrode 910 by observing depth markings 903a-f, or by comparing tracking device output and a fluoroscopic image of the target intervertebral disc to a pre-operative fluoroscopic image of the disc.

In other embodiments, an optical fiber (not shown) can be introduced into the disc. The optical fiber may be either integral with probe 900' or may be introduced as part of an ancillary device 940 via ancillary introducer 938. In this manner, the surgeon can visually monitor the interior of the intervertebral disc and the position of active electrode 910 therein.

In addition to monitoring the position of the distal portion of electrosurgical probe 900', the surgeon can also monitor whether the probe is in Coblation® mode. In most embodiments, power supply 28 (e.g., Fig. 1) includes a controller having an indicator, such as a light, an audible sound, or a liquid crystal display (LCD), to indicate whether probe 900' is generating a plasma within the disc. If it is determined that the Coblation® mechanism is not occurring, (e.g., due to an insufficiency of electrically conductive fluid within the disc), the surgeon can then replenish the supply of the electrically conductive fluid to the disc.

Fig. 44 shows steerable electrosurgical probe 950 inserted within the nucleus pulposus of an intervertebral disc. An ancillary device 940 and ancillary introducer 928 may also be inserted within the nucleus pulposus of the same disc. To facilitate the debulking of the nucleus pulposus adjacent to a contained herniation, shaft 952 (Fig. 43A) can be manipulated to a non-linear configuration, represented as 952'. Typically, shaft 955/952' is flexible over at least shaft distal end 952a so as to allow steering of active electrode 910 to a position adjacent to the targeted disc abnormality. The flexible shaft may be combined with a sliding outer shield, a sliding outer introducer needle, pull wires, shape memory actuators, and other known mechanisms (not shown) for effecting selective deflection of distal end 952a to facilitate positioning of active electrode 910 within a disc. Thus, it can be seen that the embodiment of Fig. 44 may be used for the targeted treatment of annular fissures, or any other disc abnormality in which controlled application of energy to a specific target site is indicated.

In one embodiment shaft 952 has a suitable diameter and length to allow the surgeon to reach the target disc or vertebra by introducing the shaft through the thoracic cavity, the abdomen or the like. Thus, shaft 952 may have a length in the range of from about 5.0 cm to 30.0 cm, and a diameter in the range of about 0.2 mm to about 20 mm. Alternatively, shaft 952 may be delivered percutaneously in a posterior lateral approach. Regardless of the approach, shaft 952 may be introduced via a rigid or flexible endoscope. In addition, it should be noted that the methods described with reference to Figs. 41 and 44 may also be performed in the absence of ancillary introducer 938 and ancillary device 940.

In another embodiment, the present invention involves forming one or more voids or channels within the disc, e.g., within the nucleus pulposus adjacent to the annulus fibrosus. Typically, such voids are formed electrosurgically by volumetric removal of tissue via Coblation®. Thereafter, thermal energy is applied to the tissue surface adjacent to, or surrounding, the voids to cause contraction of the tissue by shrinkage of collagen fibers within the tissue, thereby debulking the disc. Applicant has discovered that such contraction of tissue in the disc helps to reduce the pressure applied against the spinal nerves by the disc, thereby alleviating discogenic pain.

Fig. 45A shows an electrosurgical apparatus or system including a probe 1050 in combination with an introducer extension tube 1054, according to another aspect of the invention. Probe 1050 generally includes at least one active electrode 910

distal end 928a is introduced within disc 290, while extension tube distal end 1054a is advanced slightly distal to needle distal end 928a. Shaft distal end 1052a extends beyond extension tube distal end 1054a and adopts a curved configuration to access a first region, R1, of nucleus pulposus 294. Curvature of shaft distal end 1052a may result from a pre-defined bias or curve in shaft 1052, or shaft distal end 1052a may be steerable. Certain other regions of disc 290 may be accessed by shaft distal end 1052a by circumferentially rotating shaft 1052 about its longitudinal axis prior to shaft distal end 1052a being advanced distally beyond extension tube distal end 1054a (i.e., by rotating shaft 1052 while shaft 1052 lies within introducer extension tube 1054). Furthermore, a relatively large volume of tissue can be treated by rotating shaft 1052 while shaft distal end 1052a lies outside introducer extension tube 1054 and shaft distal end 1052a is in the curved configuration.

Fig. 46B schematically represents a situation wherein extension tube distal end 1054a is advanced to a second position within intervertebral disc 290. Much greater control can be exerted over the range of regions within disc 290 that can be accessed by shaft distal end 1052a when the location of introducer extension tube 1054 is selected prior to advancing shaft distal end 1052a into the disc tissue. For example, as represented in Fig. 46B, by advancing introducer extension tube 1054 distally within introducer needle 928 prior to advancing shaft distal end 1052a from introducer extension tube 1054, shaft distal end 1052a can readily access a second region R2, wherein R2 may be located remote from first region R1 (Fig. 46A). In contrast it is more problematic, if not impossible, for shaft distal end 1052a to access second region R2 while introducer extension tube 1054 is positioned in relation to the disc as shown in Fig. 46A. The inclusion of an extension device such as introducer extension tube 1054 as a component of the instant invention provides major advantages in accessing a target site within an intervertebral disc or other tissues, as compared with conventional introducer devices (e.g., needles) which lack an extension tube.

Fig. 47 is a block diagram schematically representing an electrosurgical system 1400 for delivering a fluid at a controlled temperature to a patient's tissues. System 1400 includes an electrosurgical probe 1401 having a shaft 1402 and an electrode assembly 1420. Typically, electrode assembly 1420 is disposed at the distal or working end of shaft 1402, and includes at least one active electrode, and a return electrode

end 1502a and a shaft proximal end 1502b. An electrode assembly 1520 is disposed at shaft distal end 1502a. Electrode assembly 1520 comprises at least one active electrode 1510, and a return electrode 1518 spaced proximally from active electrode 1510 by an electrically insulating spacer or electrode support 1512. Probe 1500 further includes a fluid delivery unit and an aspiration unit. The fluid delivery unit comprises a proximal fluid delivery tube 1536 coupled to a fluid delivery lumen 1534, and terminates distally in a fluid delivery port 1532. The fluid delivery unit receives fluid at a controlled temperature (e.g., Figs. 47, 48), and is adapted for delivering the fluid (represented as solid arrows) from shaft distal end 1502a to a patient's body. In order to prevent, or minimize, heat loss or gain between the fluid in transit through probe 1500 and the environment, fluid delivery tube 1536, shaft 1502, and/or other components may be thermally insulated, or otherwise adapted to minimize temperature fluctuations of the fluid.

Again with reference to Fig. 49, the aspiration unit comprises a proximal aspiration tube 1546 coupled to an aspiration lumen 1544, and a distal aspiration port 1542 at shaft distal end 1502a. The aspiration unit is adapted for retrieving or withdrawing a quantity of the fluid delivered via the fluid delivery unit from the region of shaft distal end 1502a within the patient's body. Probe 1500 further includes a handle 1504 affixed to shaft proximal end 1502b. Handle 1504 typically houses a connection block 1506. Connection block 1506 provides a convenient mechanism for independently coupling active electrode(s) 1510 and return electrode 1518 to a high frequency power supply (e.g., Fig. 47). Probe 1500 may optionally further include a temperature sensor unit 1550, disposed at shaft distal end 1502a, for measuring a temperature of the milieu at shaft distal end 1502a.

Fig. 50 represents delivery and withdrawal of a preheated fluid to/from a void within an intervertebral disc, according to one embodiment of the invention. As shown, an introducer device 1501 is inserted into a disc 290. Typically, introducer device 1501 is advanced towards the disc in a posterior lateral approach. An electrosurgical and/or fluid delivery apparatus 1500' is passed within introducer device 1501 such that a shaft distal end 1502'a of apparatus 1500' is located in disc 290. Apparatus 1500' may include an electrode assembly (e.g., Fig. 49) coupled to a high frequency power supply, for forming a void, VO within disc 290. Alternatively, apparatus 1500' may lack ablative capacity, and void, VO may be formed by a separate device (e.g., an electrosurgical probe as described hereinabove with reference to Figs. 26A-35, 37, 38, 41-45B) prior to

void, VO depicted in Fig. 50 is approximately ovoid, various other shapes, e.g., spheres, elongated channels, etc., are also within the scope of the invention.

Fig. 51 is a block diagram schematically representing a fluid delivery system 1600 for delivering a fluid at a controlled temperature to a patient's tissues, according to another embodiment of the invention. System 1600 includes a shaft 1602, a fluid delivery unit 1630, and an aspiration unit 1640. Typically, fluid delivery unit 1630 and aspiration unit 1640 are integral with shaft 1602 (e.g., Fig. 52). Fluid delivery unit 1630 is adapted for delivering a fluid at a controlled temperature in at least close proximity to a target tissue, while aspiration unit 1640 is adapted for withdrawing a quantity of the fluid delivered by fluid delivery unit 1630. System 1600 further includes a fluid source unit 1660, coupled to fluid delivery unit 1630, for providing a fluid at a specific temperature to fluid delivery unit 1630. Fluid source unit 1660 typically includes a temperature control unit, and other elements analogous to those described hereinabove with reference to fluid source unit 1460' of Fig. 48. System 1600 may further include a temperature sensor unit 1650 for measuring a temperature of the milieu at the distal end of shaft 1602, and a temperature display unit 1652 for displaying (to the surgeon) the temperature of the milieu at the distal end of shaft 1602. In the embodiment of Figs. 51 and 52, the apparatus lacks an electrode assembly. Thus, in situations where it is required to form a void adjacent to a target tissue prior to treatment of the target tissue by exposure to a preheated fluid, system 1600 and apparatus 1700 (Fig. 52) may be used in conjunction with a separate instrument (e.g., an electrosurgical probe as described hereinabove with reference to Figs. 26A-35) for forming such a void.

Fig. 52 is a side view of a fluid delivery and fluid retrieval apparatus for circulating a fluid at a controlled temperature within a patient's tissues, according to one embodiment of the invention. Apparatus 1700 includes a shaft 1702 having a shaft distal end portion 1702a and a shaft proximal end portion 1702b. Apparatus 1700 further includes a fluid delivery unit and an aspiration unit integral with shaft 1702. The fluid delivery unit comprises a proximal fluid delivery tube 1736 coupled to a fluid delivery lumen 1734, and terminates distally in a fluid delivery port 1732. The fluid delivery unit is adapted for delivering a fluid (represented as solid arrows) from shaft distal end 1702a to a patient's body. The aspiration unit comprises a proximal aspiration tube 1746 coupled to an aspiration lumen 1744, and a distal aspiration port 1742 at shaft distal end 1702a. The aspiration unit is adapted for retrieving or withdrawing a quantity of the fluid delivered via the fluid delivery unit from the region of shaft distal end 1702a. Typically,

temperature via heat exchange with the introduced fluid. In one embodiment, the fluid is introduced into the void formed according to step 1802. Typically, the fluid is introduced into at least close proximity to the target tissue, e.g., into the void, via a fluid delivery unit integral with the electrosurgical probe (e.g., Fig. 49). Alternatively, the fluid may be delivered via a fluid delivery unit of an ancillary device (e.g., apparatus 1700, Fig. 52). Step 1808 involves adjusting the temperature of the target tissue via heat exchange between the fluid and the target tissue. Fluid delivered to a void within a patient's body will tend towards ambient temperature (i.e., body temperature). In order to maintain the temperature of the fluid within the void at, or close to, a desired temperature for treating the target tissue, step 1810 involves the withdrawal of fluid from the void concurrently with introduction of fluid in step 1806. In this manner, fluid within the void is at substantially the controlled temperature, and target tissue adjacent or in close proximity to the fluid undergoes a change in temperature. The actual treatment temperature experienced by the target tissue will depend, *inter alia*, on the controlled temperature of the fluid, the rates of introduction and withdrawal (or circulation) of the fluid, and the time of "exposure" of the target tissue to the fluid (i.e., the length of time that the fluid is circulated through the void). By adjusting these or other parameters, a suitable temperature regime for treating the target tissue can be provided. After the target tissue has been treated for an appropriate time period at a suitable temperature, e.g., to effect contraction of collagen fibers within the target tissue, step 1806 may be terminated, and any excess fluid (e.g., saline) may be removed from the vicinity of the target tissue according to step 1810.

Fig. 54 schematically represents a series of steps involved in a method for treating a target tissue within an intervertebral disc by delivering a preheated fluid to the disc, according to another embodiment of the invention, wherein step 1900 involves inserting an introducer device into the disc. In one embodiment, the introducer device is inserted into the disc in a posterior lateral approach. According to one aspect of the invention, the introducer device includes an introducer extension tube adapted for passage within an introducer needle, and the introducer extension tube is further adapted for passing a shaft distal end of an electrosurgical probe therethrough. Step 1902 involves introducing an electrosurgical probe into the disc via the introducer device. Step 1904 involves positioning an active electrode of the electrosurgical probe in at least close proximity to the target tissue. The target tissue may be in the inner nucleus pulposus or in the outer annulus fibrosus of the disc. In one embodiment, the electrosurgical probe is

delivery unit via one or more pumps and/or valves. The fluid delivery unit may be integral with the electrosurgical probe, or may be on a separate device.

Step 1910 involves delivering the preheated fluid to the void. Typically, the void is in at least close proximity to the target tissue. Due to heat exchange between the preheated fluid in the void and the target tissue, the target tissue is elevated to a treatment temperature. For the contraction of collagen containing target tissue, e.g., nucleus pulposus tissue, the treatment temperature is often in the range of from about 60°C to 70°C. As noted hereinabove, fluid delivered to a void within a patient's body will tend towards ambient temperature (i.e., body temperature). In order to attain and maintain a suitable treatment temperature of the target tissue, it is generally necessary to replenish the supply of preheated fluid, by continuing step 1910, during the procedure. Step 1912 involves removing at least a portion of the fluid from the void in order to compensate for fluid delivered during step 1910. In this manner, a substantially constant treatment temperature of the tissue can be achieved for a defined period of time.

Although the invention has been described primarily with respect to the contraction of collagen containing tissue of intervertebral discs by delivery of preheated fluid to a void, it is to be understood that the methods and apparatus of the invention are also applicable to the treatment of other tissues, organs, and bodily structures by delivering fluid at various temperatures above, or below, normal body temperature. Thus, while the exemplary embodiments of the present invention have been described in detail, by way of example and for clarity of understanding, a variety of changes, adaptations, and modifications will be obvious to those of skill in the art. Therefore, the scope of the present invention is limited solely by the appended claims.

9. The method of claim 7, wherein said step b) comprises delivering the preheated fluid to the void via a fluid delivery unit, wherein the fluid delivery unit is integral with the electrosurgical probe.

10. The method of claim 7, wherein said step b) comprises delivering the preheated fluid to the void via a fluid delivery system, wherein the fluid delivery system is separate from the electrosurgical probe.

11. The method of claim 1, wherein said step b) comprises delivering saline to the void, the saline at a temperature in the range of from about 60°C to 70°C.

12. The method of claim 1, wherein said step b) comprises delivering the preheated fluid to the void at a regulated rate, and the method further comprises:

d) withdrawing the fluid from the void, whereby the fluid is circulated through the void at a substantially constant temperature.

13. A method for treating an intervertebral disc, comprising:

a) forming a void in at least close proximity to a target tissue within the intervertebral disc; and

b) delivering a preheated fluid to the void, wherein at least a portion of the target tissue is heated to a temperature in the range of from about 45°C to 90°C, whereby collagen fibers within the target tissue undergo shrinkage.

14. The method of claim 13, wherein at least a portion of the target tissue is heated to a temperature in the range of from about 60°C to 70°C.

15. The method of claim 13, wherein the target tissue is heated via heat exchange between the preheated fluid and the target tissue.

16. The method of claim 13, wherein said step a) comprises forming a void in the nucleus pulposus.

b) introducing a distal end of an electrosurgical probe into the disc via the introducer device;

c) positioning an active electrode of the probe in at least close proximity to a target tissue of the disc;

d) applying a high frequency voltage between the active electrode and a return electrode, the high frequency voltage sufficient to form a void in at least close proximity to the target tissue;

e) heating a biocompatible fluid to a controlled temperature to provide a preheated fluid;

f) delivering the preheated fluid to the void; and

g) while performing said step f), removing at least a portion of the preheated fluid from the void, whereby the preheated fluid in the void is maintained at substantially the controlled temperature.

25. The method of claim 24, wherein the preheated fluid in the void raises the temperature of at least a portion of the target tissue to a treatment temperature.

26. The method of claim 25, wherein the treatment temperature is sufficient to cause contraction of at least a portion of the target tissue.

27. The method of claim 25, wherein the treatment temperature is in the range of from about 60°C to 70°C.

28. The method of claim 24, wherein the biocompatible fluid comprises an aqueous solution.

29. The method of claim 24, further comprising:

h) after performing said steps f) and g) for an appropriate period of time, discontinuing said step f), and removing any excess preheated fluid from the void.

30. The method of claim 24, further comprising:

37. The method of claim 35, wherein the target tissue is exposed to a temperature in the range of from about 45°C to 90°C.

38. The method of claim 35, wherein the void is formed within an intervertebral disc.

39. An electrosurgical apparatus, comprising:

a shaft having a shaft distal end;

an electrode assembly at the shaft distal end;

a fluid delivery unit including a fluid delivery tube; and

a fluid source unit coupled to the fluid delivery tube, the fluid source unit providing a fluid at a controlled temperature to the fluid delivery unit, wherein the fluid source unit includes a fluid reservoir and a temperature control unit coupled to the fluid reservoir.

40. The apparatus of claim 39, wherein the fluid source unit further includes a flow control unit in communication with the fluid reservoir.

41. The apparatus of claim 39, wherein the fluid source unit further includes a heating unit for heating the fluid in the fluid reservoir and a cooling unit for cooling the fluid in the fluid reservoir, the temperature control unit coupled to the heating unit and to the cooling unit.

42. The apparatus of claim 39, further comprising a high frequency power supply coupled to the electrode assembly, the electrode assembly adapted for electrosurgical ablation of tissue.

43. The apparatus of claim 39, wherein the fluid delivery unit comprises a fluid delivery lumen in communication with a fluid delivery tube, the fluid delivery lumen terminating distally in a fluid delivery port.

44. The apparatus of claim 39, wherein the fluid delivery unit is adapted for delivering the fluid from the shaft distal end to a patient's body.

45. The apparatus of claim 39, further comprising an aspiration unit adapted for aspirating the fluid from the vicinity of the shaft distal end.

52. The system of claim 51, wherein the fluid source unit further includes a heating unit for heating the fluid, the temperature control unit coupled to the heating unit.

53. The system of claim 51, wherein the fluid source unit further includes a cooling unit for cooling the fluid, the temperature control unit coupled to the cooling unit.

54. The system of claim 48, further comprising a temperature sensor unit on the shaft distal end portion, the temperature sensor for measuring the temperature of the fluid in at least close proximity to the target tissue.

55. The system of claim 48, further comprising an electrode assembly disposed at the shaft distal end portion, the electrode assembly adapted for ablation of tissue.

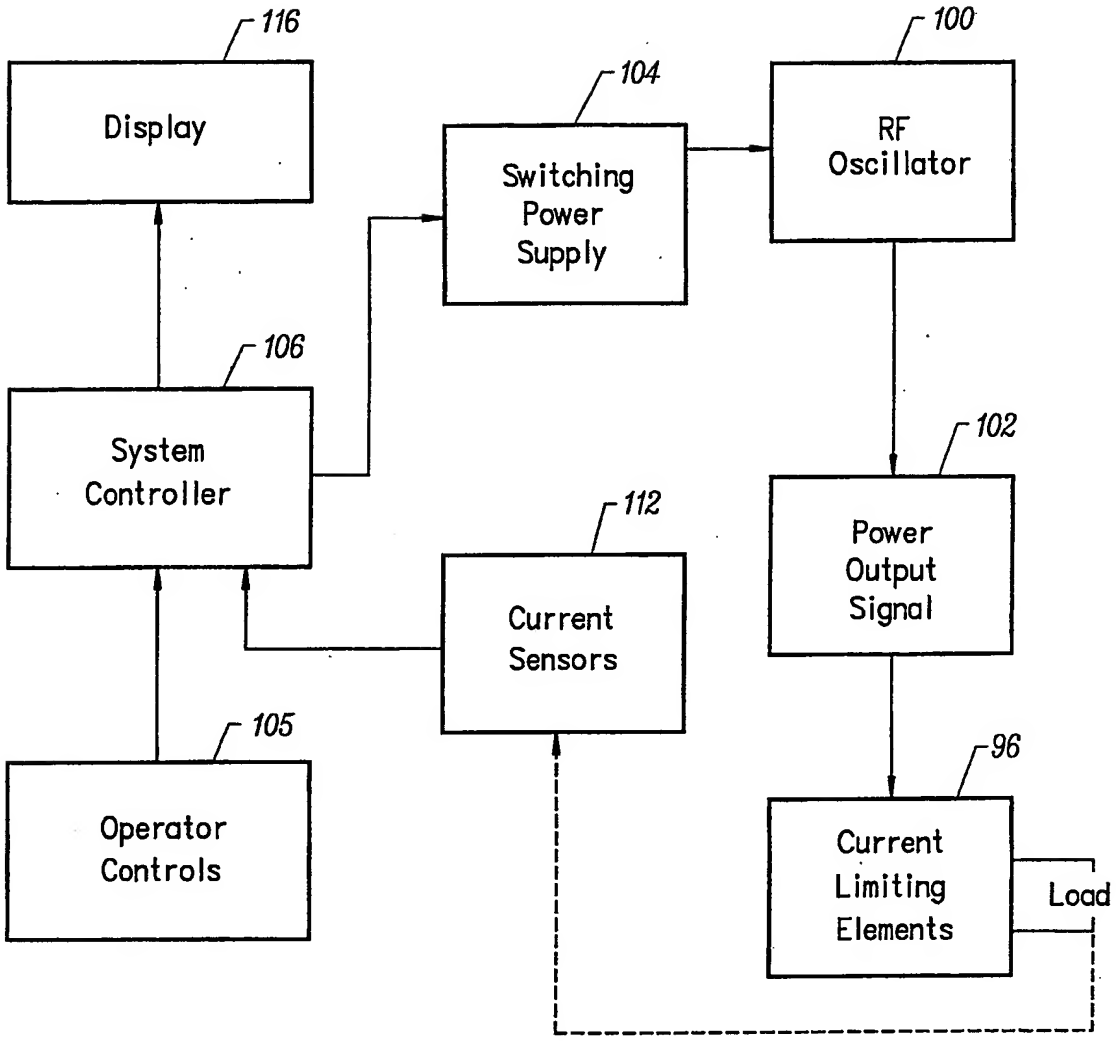
116
Display
104
Switching Power Supply
100
RF Oscillator
106
System Controller
112
Current Sensors
102
Power Output Signal
105
Operator Controls
96
Current Limiting Elements
Load

FIG. 2

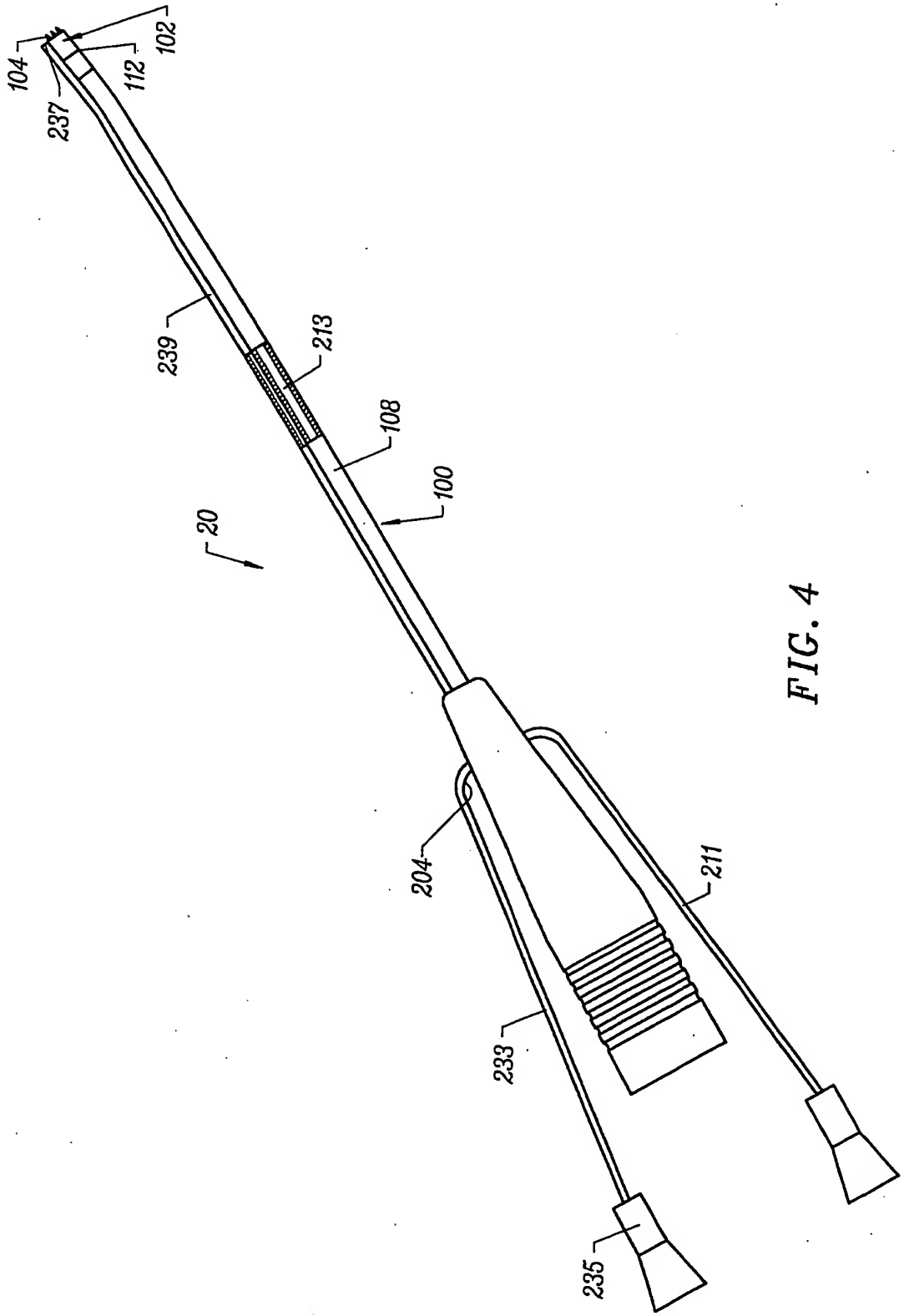

FIG. 4

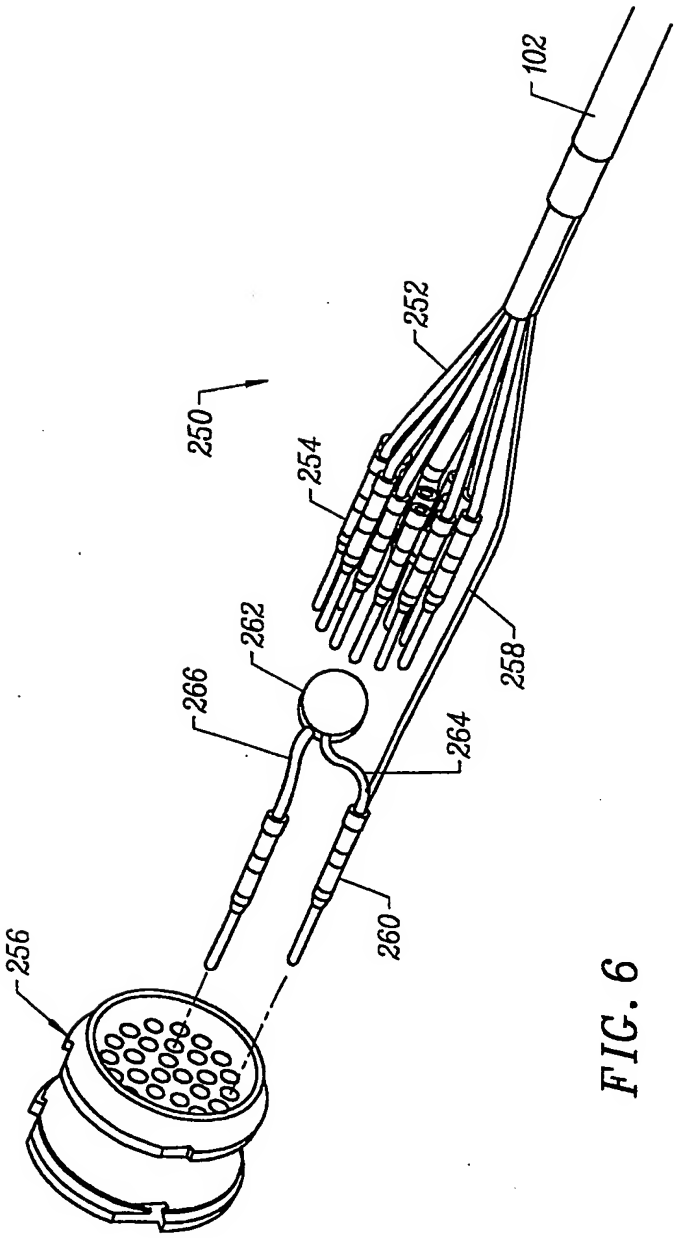

FIG. 6

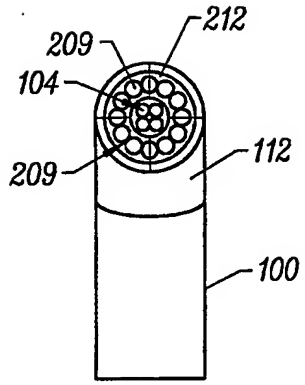

FIG. 7B

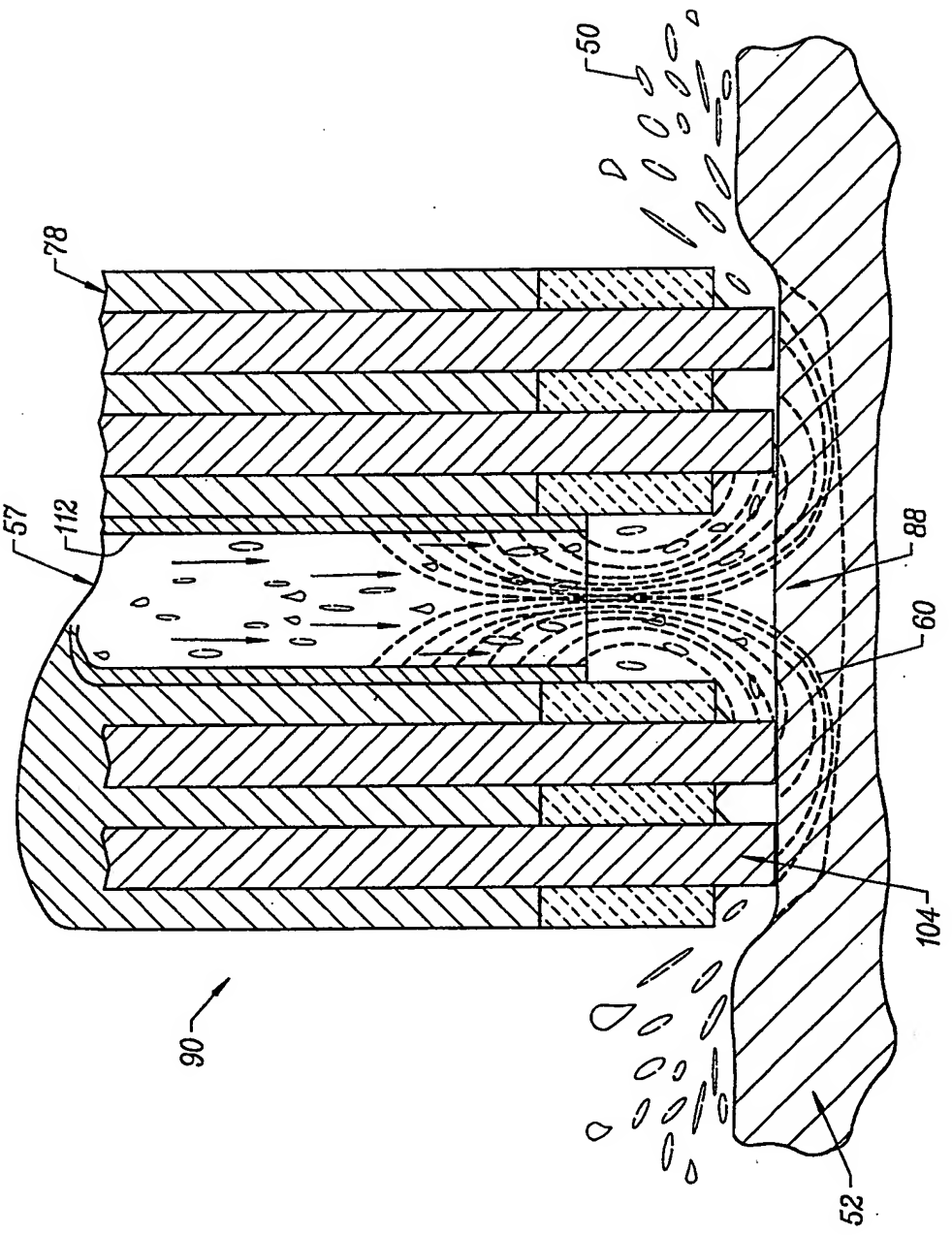

FIG. 8B

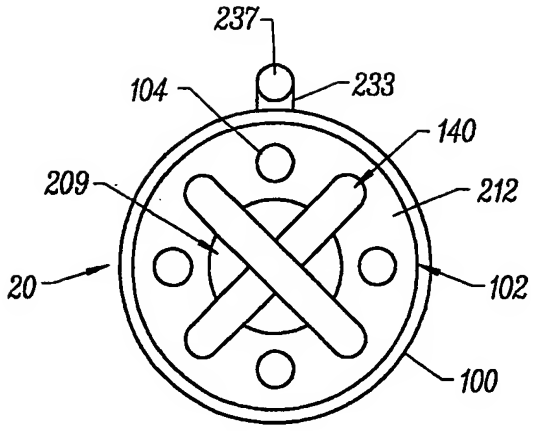
237
104
233
140
209
212
20
102
100

FIG. 9

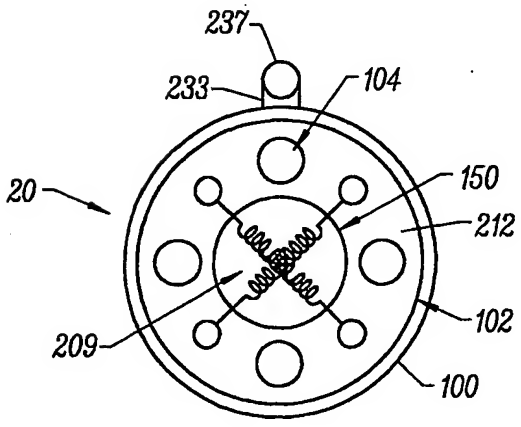
237
233
104
20
150
212
102
209
100

FIG. 10

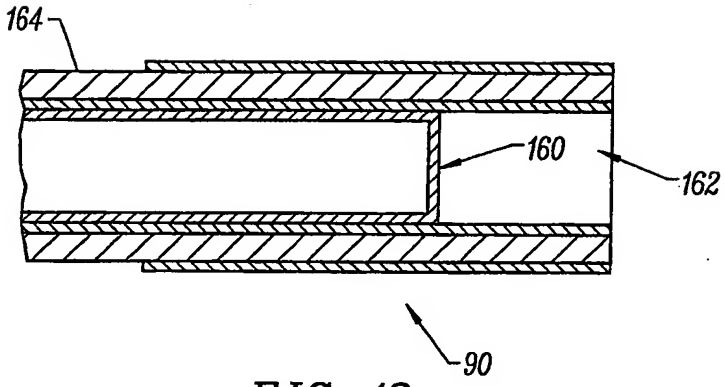

FIG. 13

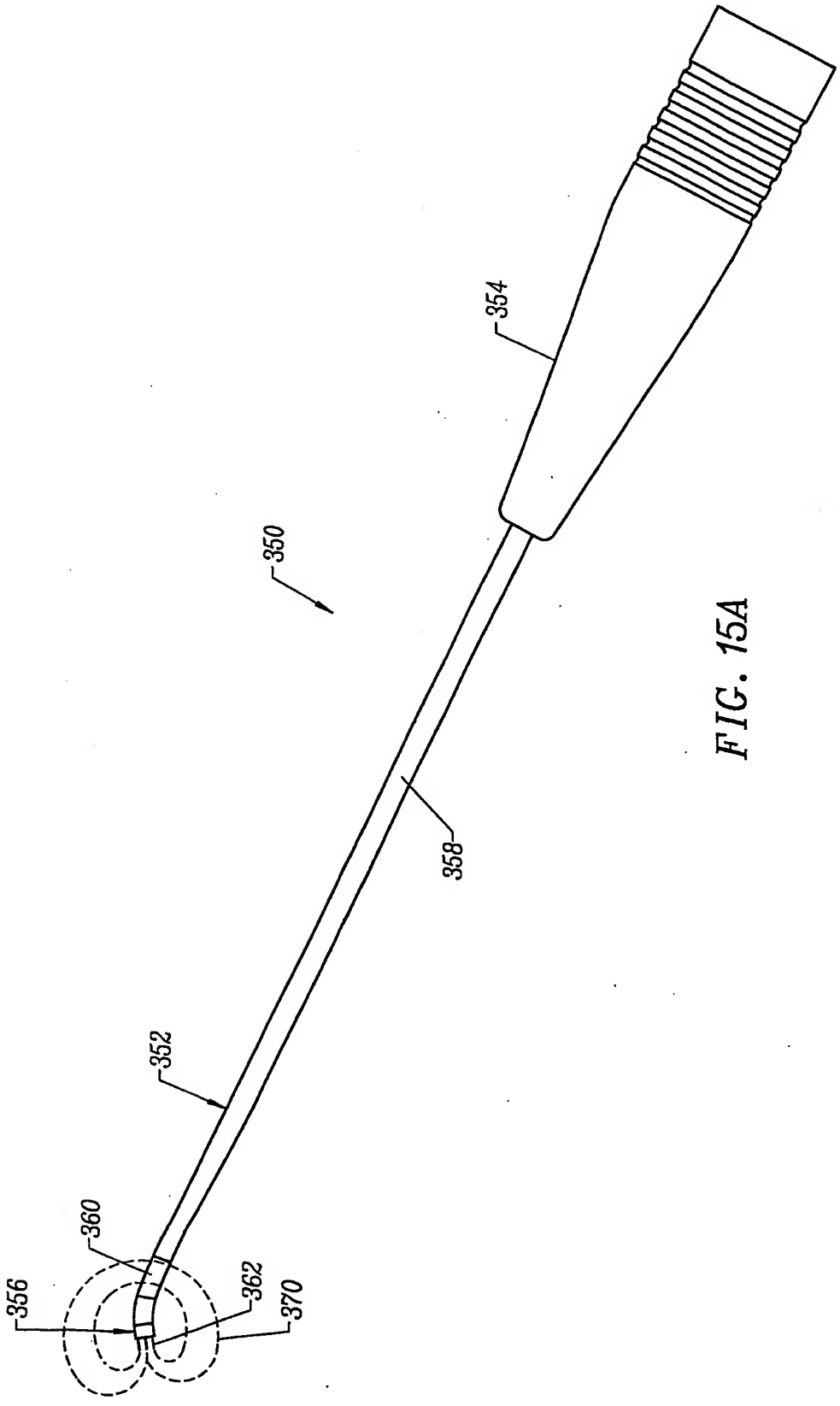

FIG. 15A

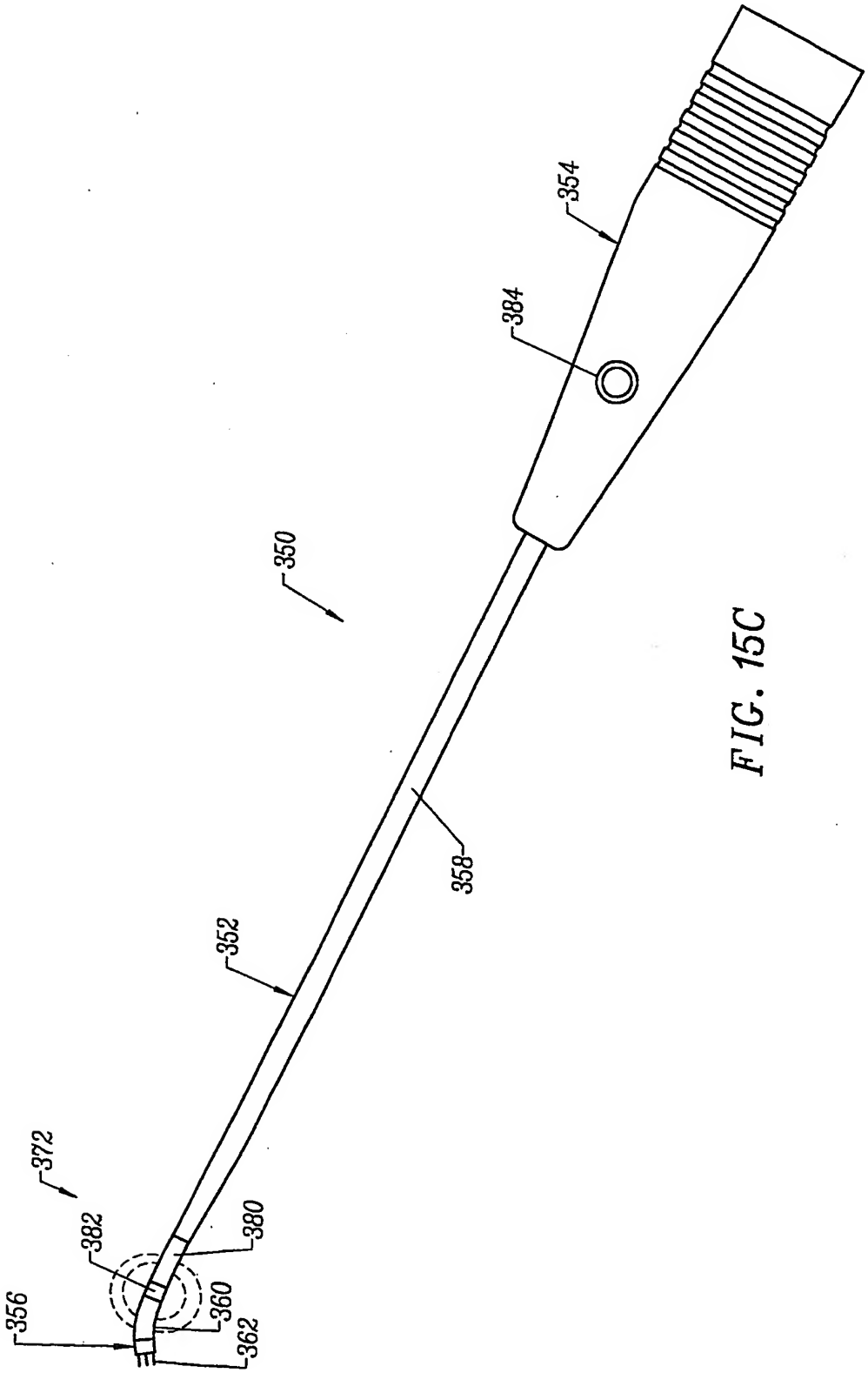

FIG. 15C

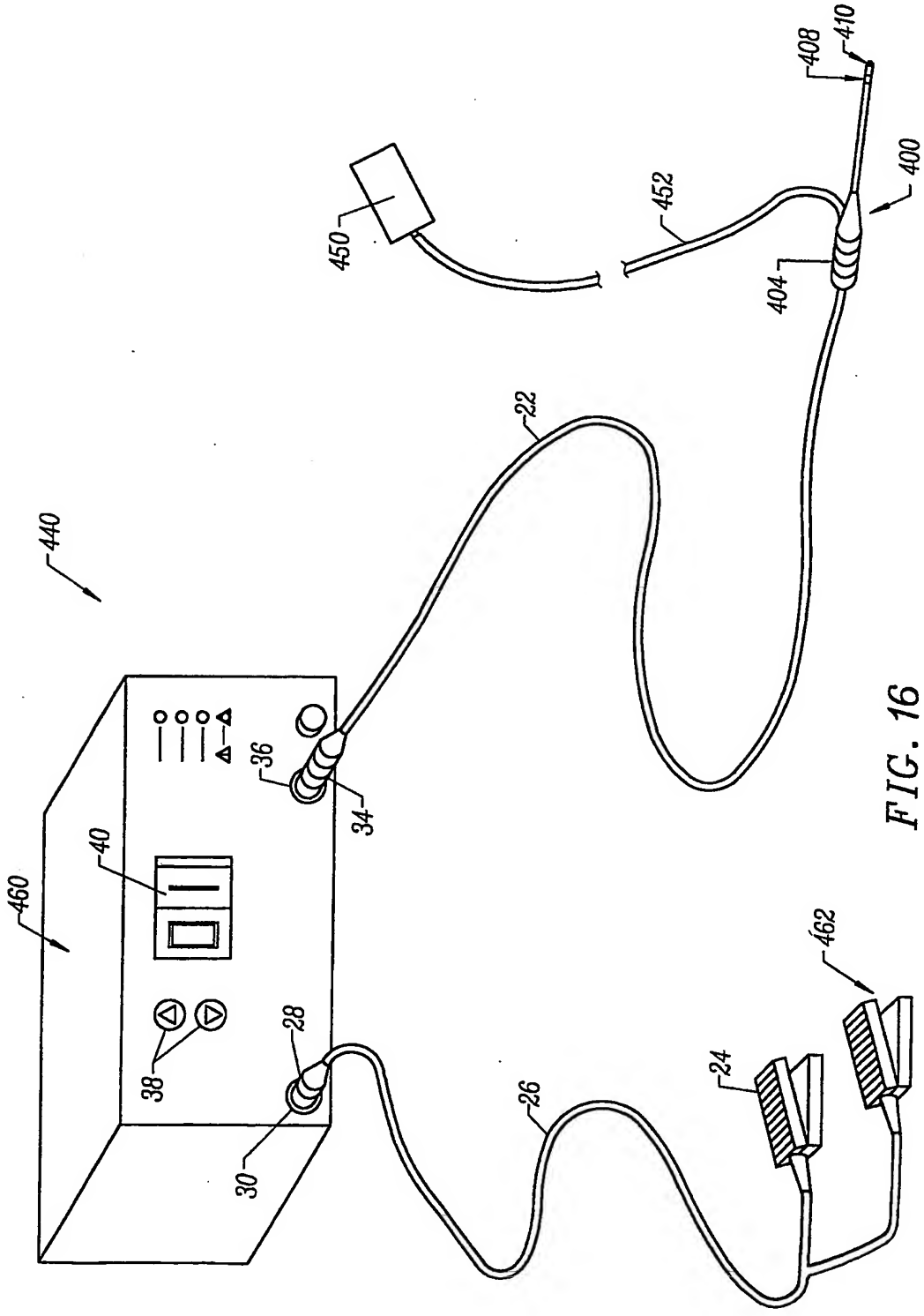

FIG. 16

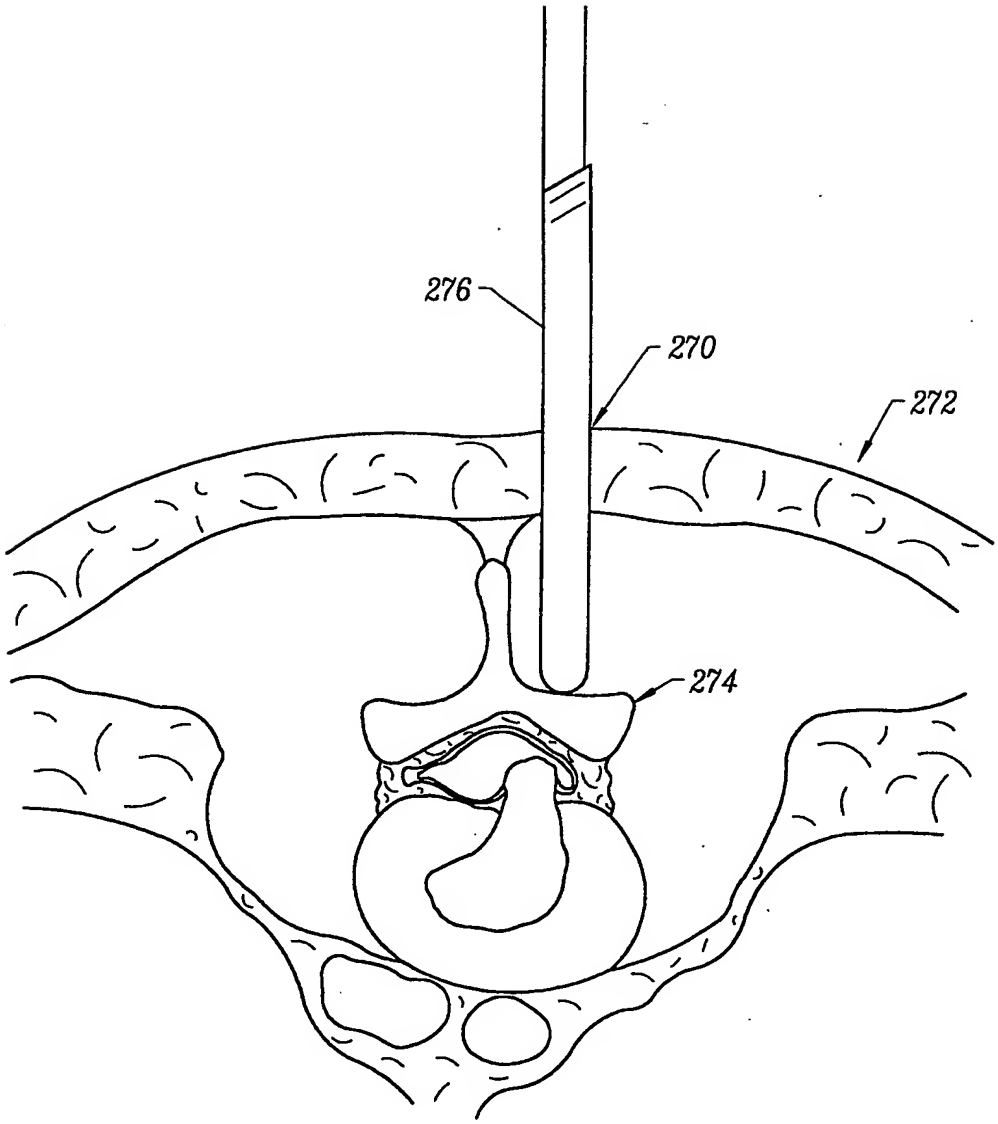

FIG. 18

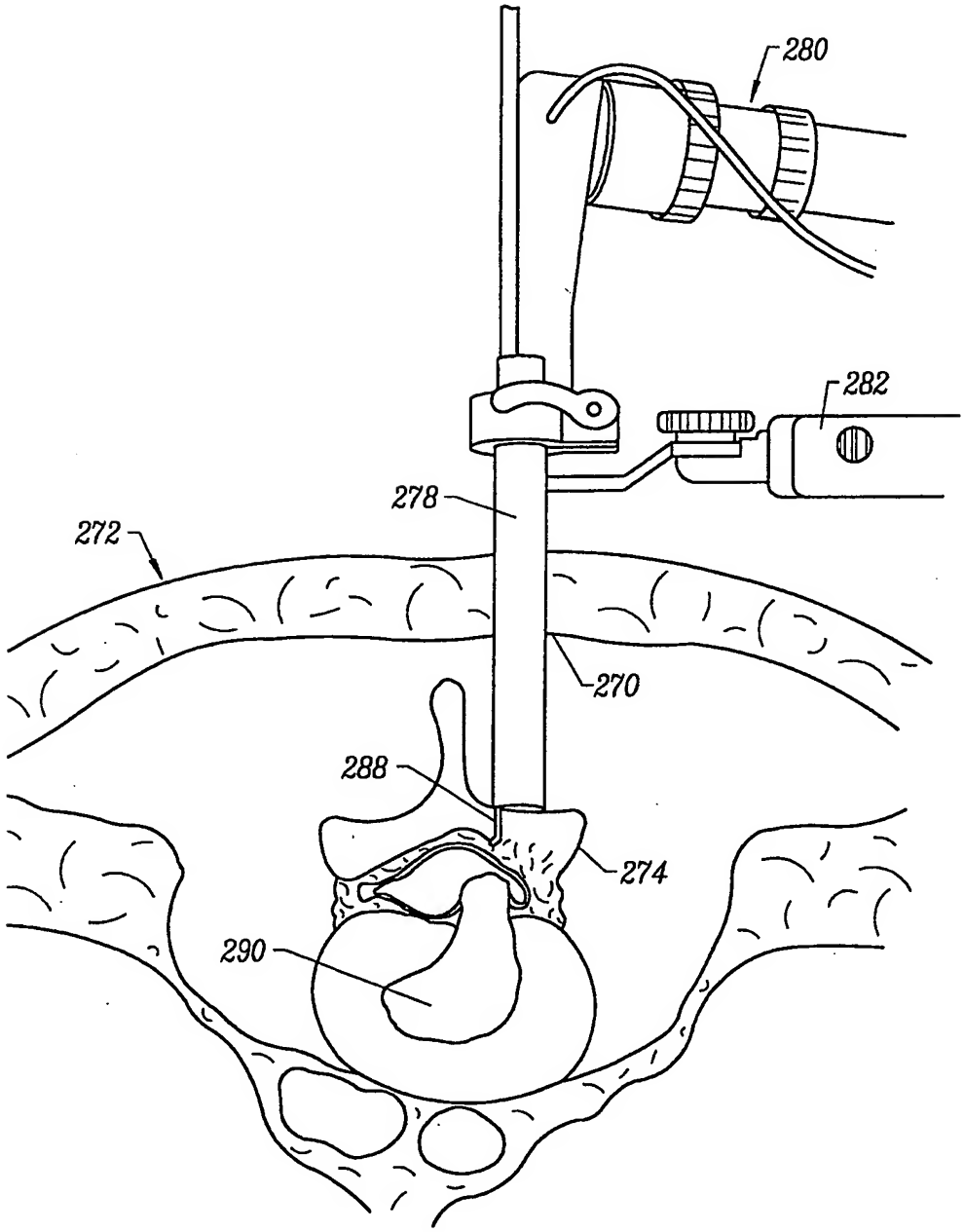

FIG. 20

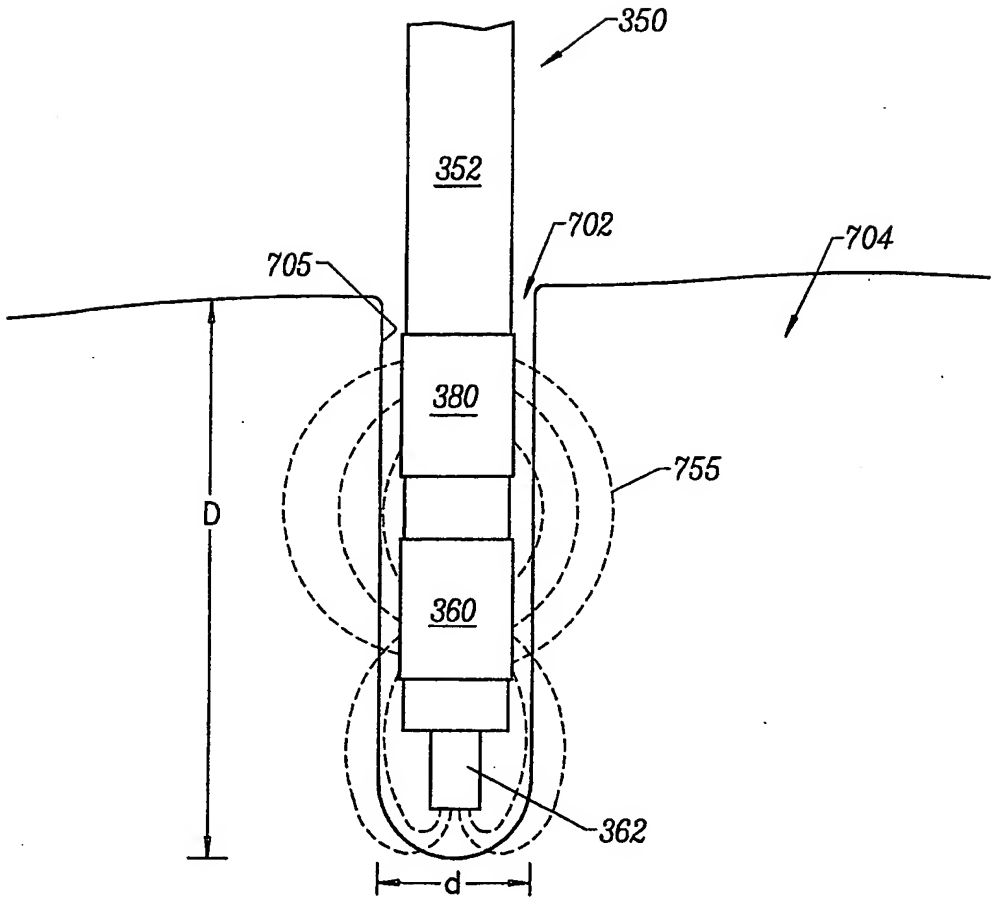

FIG. 22

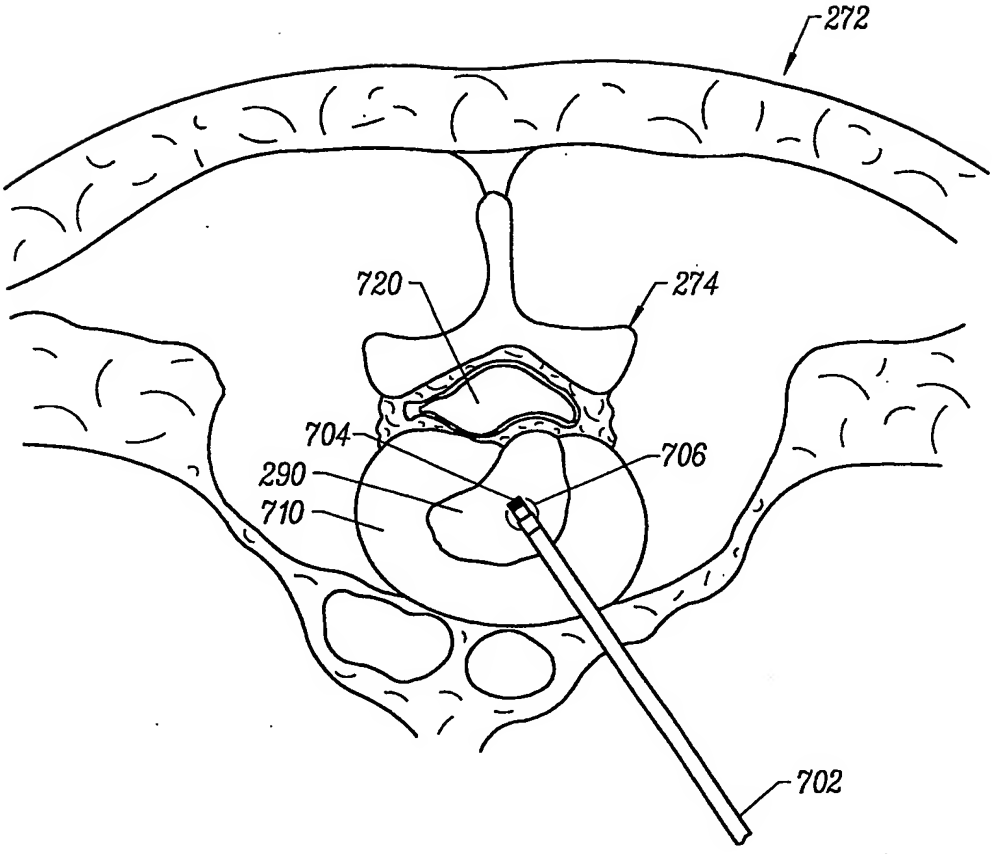

FIG. 24

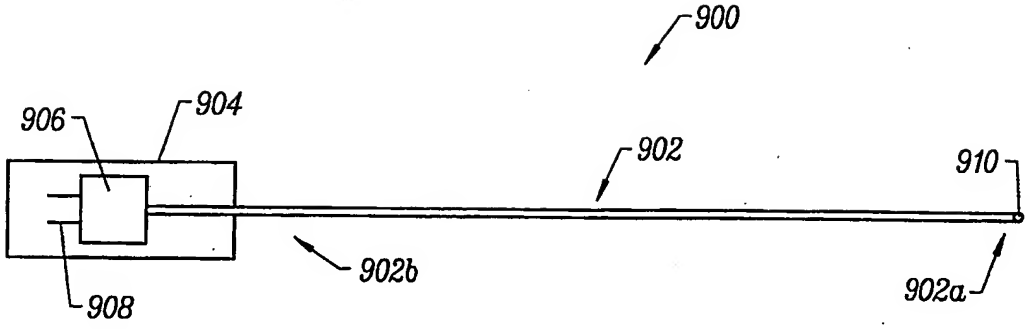

FIG. 26A

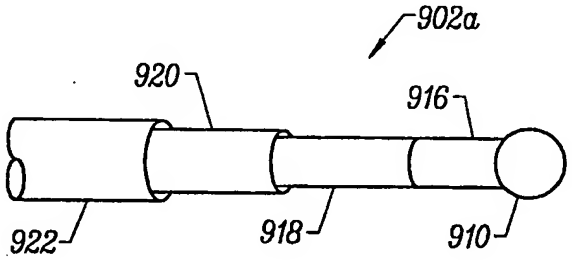

FIG. 26B

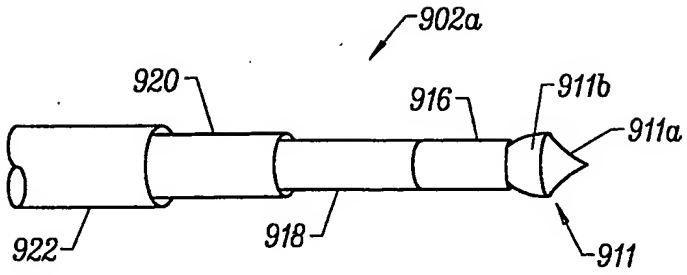

FIG. 28A

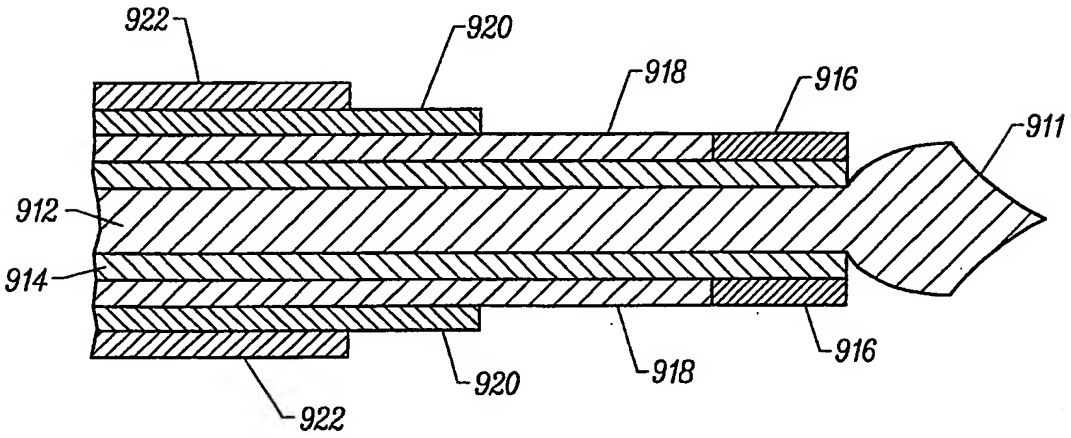

FIG. 28B

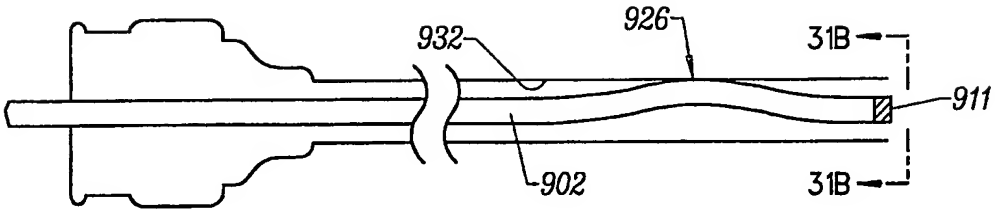

FIG. 31A

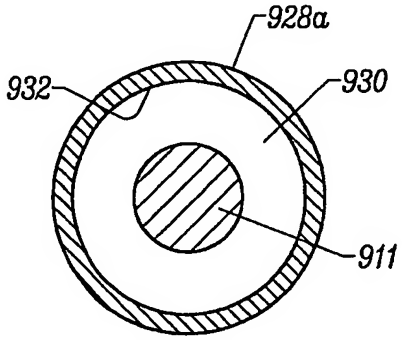

FIG. 31B

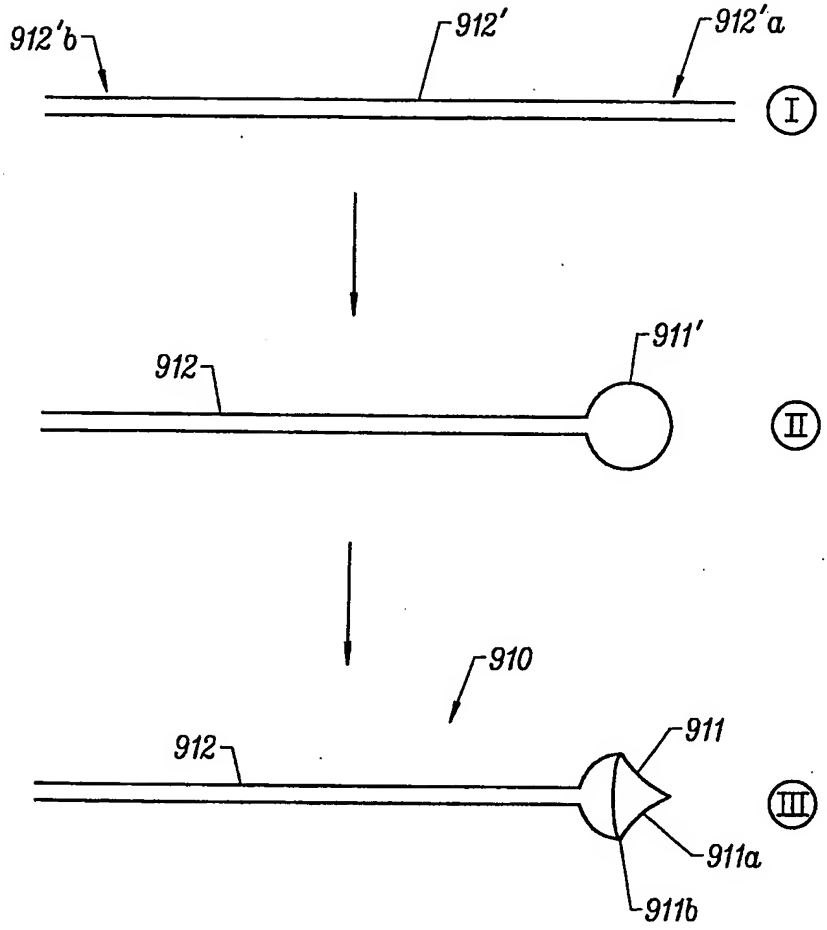

FIG. 33

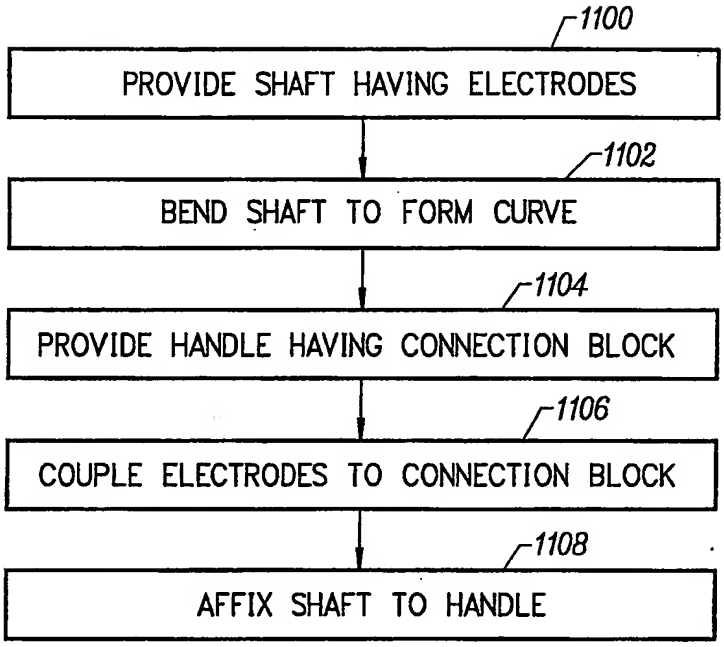
1100
PROVIDE SHAFT HAVING ELECTRODES
1102
BEND SHAFT TO FORM CURVE
1104
PROVIDE HANDLE HAVING CONNECTION BLOCK
1106
COUPLE ELECTRODES TO CONNECTION BLOCK
1108
AFFIX SHAFT TO HANDLE

FIG. 35

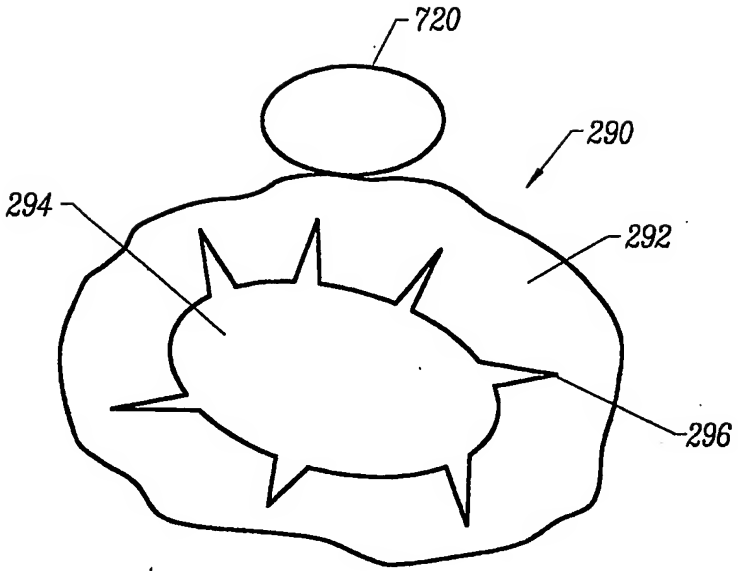

FIG. 36C

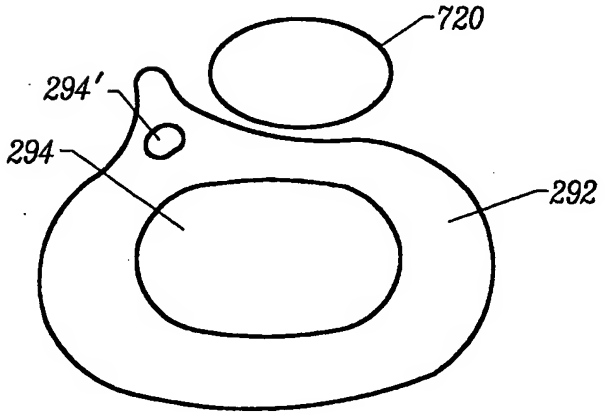

FIG. 36D

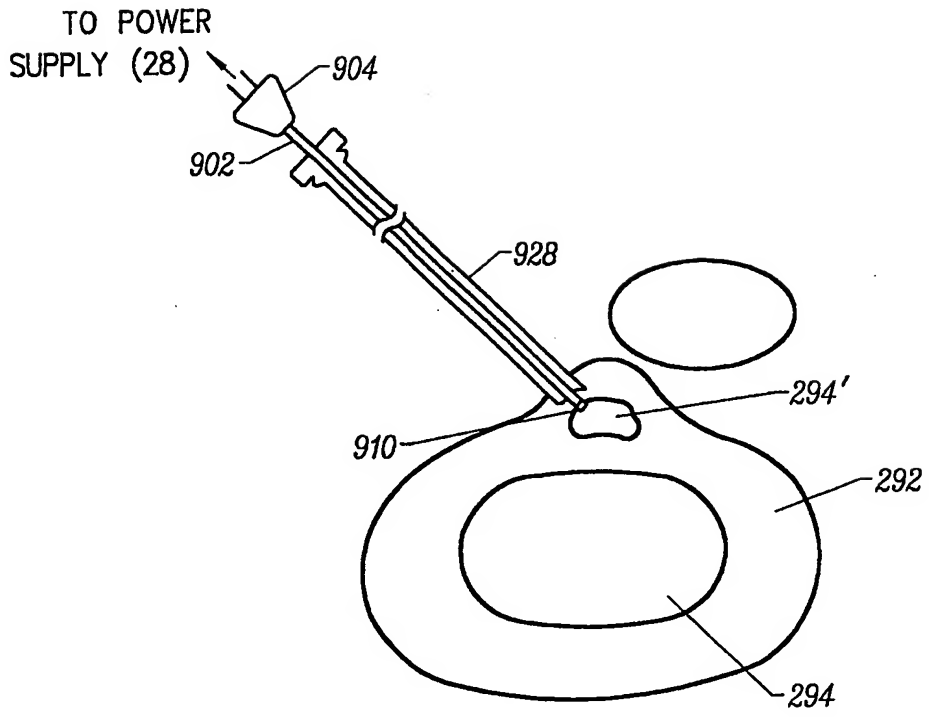

FIG. 38

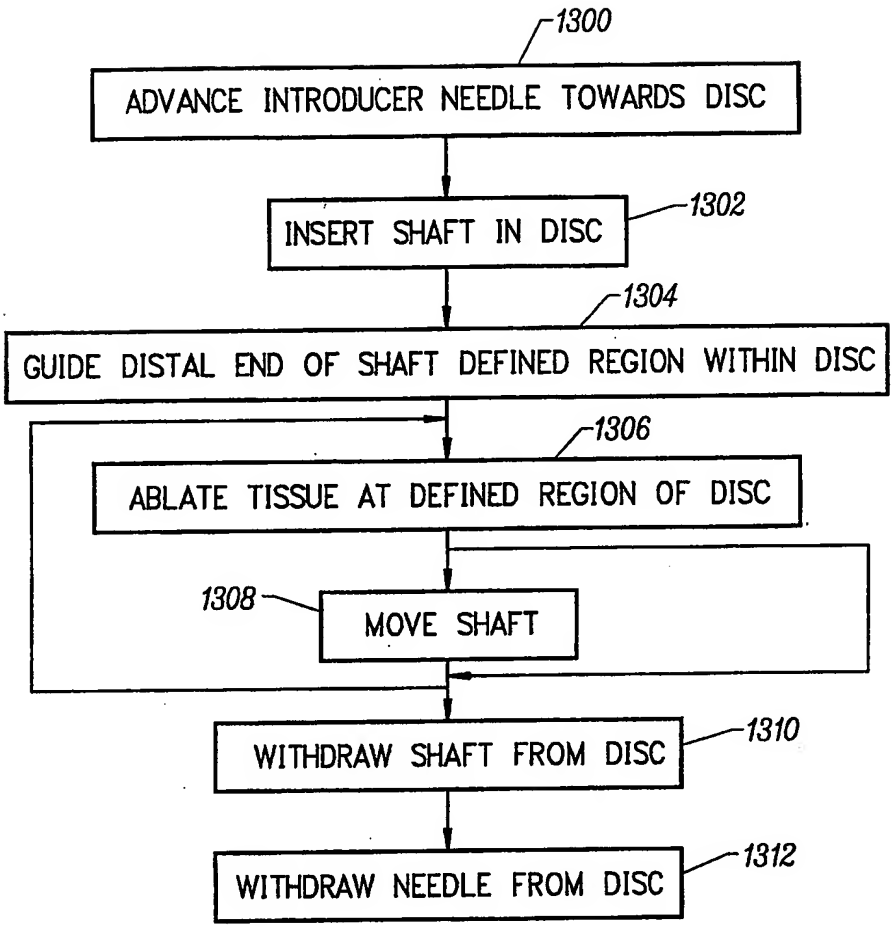
1300
ADVANCE INTRODUCER NEEDLE TOWARDS DISC
INSERT SHAFT IN DISC
1302
1304
GUIDE DISTAL END OF SHAFT DEFINED REGION WITHIN DISC
1306
ABLATE TISSUE AT DEFINED REGION OF DISC
1308
MOVE SHAFT
WITHDRAW SHAFT FROM DISC
1310
WITHDRAW NEEDLE FROM DISC
1312

FIG. 40

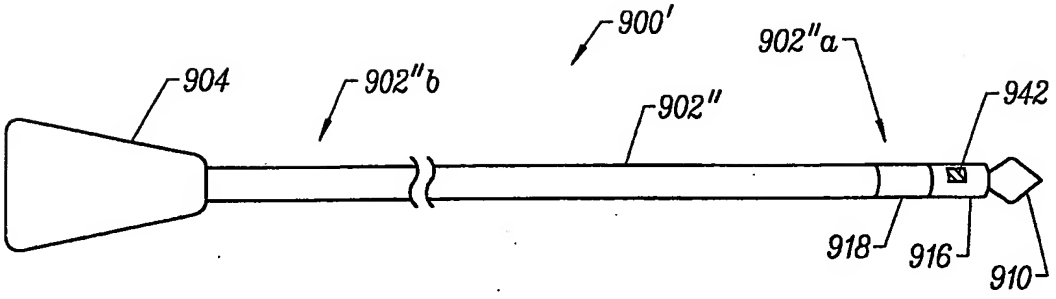

FIG. 42

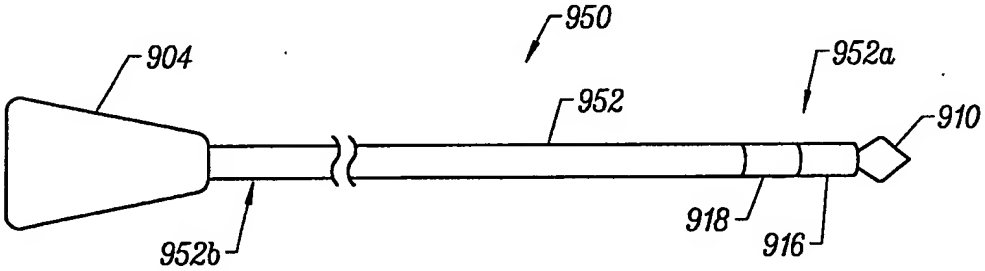

FIG. 43A

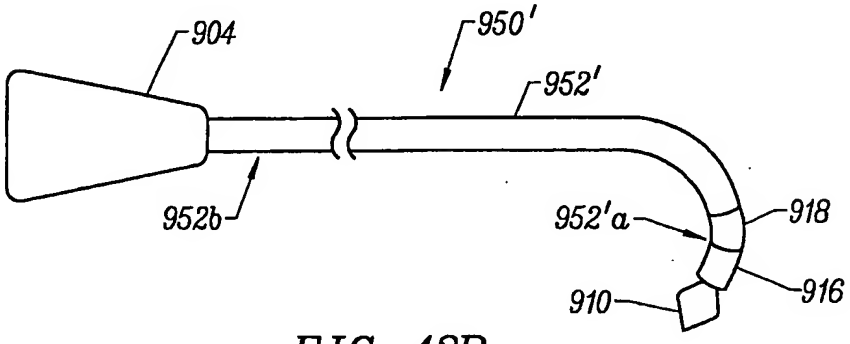

FIG. 43B